

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	) ) MDL NO. 1456 ) Civil Action No. 01-12257-PBS ) Subcategory Case No: 03-10643-PBS
THIS DOCUMENT RELATES TO:	) ) Judge Patti B. Saris
<i>The City of New York, et al.</i>	) )
v.	) )
<i>Abbott Laboratories, et al.</i>	) )

**PLAINTIFFS' REPLY LOCAL RULE 56.1 STATEMENT OF UNDISPUTED  
MATERIAL FACTS AS TO IVAX CORPORATION AND IVAX PHARMACEUTICALS  
INC.**

Pursuant to Rule 56.1 of the Local Rules of this Court, plaintiffs hereby submit their Reply Local Rule 56.1 Statement of Undisputed Material Facts As To Defendants Ivax Corporation and Ivax Pharmaceuticals, Inc. (collectively "Ivax").

**I. IVAX SPECIFIC FACTS**

**1. The Ivax drugs and NDCs that have been examined on this motion are set forth in Exhibit A hereto. This exhibit also sets forth Ivax's Published AWP and WACs for these Drugs and NDCs, any operative Federal Upper Limit ("FUL") and Ivax's AMPs. The exhibit notes which NDCs are associated with package sizes that set the FUL.**

Ivax's Response to Alleged Fact No. 1:

Disputed. Ivax does not dispute that Exhibit A to Plaintiffs' Ivax-Specific Statement purports to (1) list the Ivax drugs and NDCs that Plaintiffs have examined in connection with their motion, (2) set forth Ivax's published AWP and WACs for these drugs and NDCs, any operative FUL, and Ivax's AMPs, and (3) note which NDCs are associated with the package sizes that set the FUL. Ivax disputes that Plaintiffs' Exhibit is an accurate and/or complete portrayal of the AWP and WAC prices, the operative FULs, and AMPs for these Ivax drugs and NDCs for any given time period. Ivax further disputes that Plaintiffs' Exhibit accurately reflects or updates the prices for these Ivax drugs and NDCs and/or the dates that they become effective. Further, Ivax objects to Alleged Fact No. 1 on the grounds that Plaintiffs fail, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer admissible evidence in support of this

statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer “facts that would be admissible in evidence”); *O’Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006) (disregarding “purported statements of ‘fact’ not properly supported by citations to the record” in summary judgment pleadings). Moreover, Ivax objects to Alleged Fact No. 1 insofar as it lacks adequate foundation. *See* Fed. R. Evid. 602.

#### **PLAINTIFFS’ REPLY TO STATEMENT #1:**

Ivax’s dispute as to the data in Exhibit A not being properly supported by evidence in the record is baseless. Plaintiffs properly cited Ivax as the source of the Ivax AMP data and the First Databank NDDF data file (Alabama Production, FDB-AWP 030785 – 030795) as the source of all other data (*see* Exhibit A at 28), which is the same source cited by Ivax’s expert Dr. Addanki. *See* Affidavit of Dr. Sumanth Addanki dated May 15, 2009 [Dkt# 6056] at Exhibit 2 (identifying “First DataBank (Alabama Production) Data and NDDF (National Drug Data File)<sup>TM</sup> Documentation Manual (Rev. April 2000)” as a Data source). *See also* Reply Affidavit of Joanne M. Cicala, sworn to June 30, 2009 and submitted in further support of plaintiffs’ motion for partial summary judgment at ¶2, which is incorporated herein.

Ivax disputes that Plaintiffs’ Exhibit is accurate and/or complete but offers no evidence in support as required by Rule 56.1. Ivax’s other objections concerning admissibility are likewise baseless and unsubstantiated. No further reply is required.

**2. The specific Ivax drugs at issue are the Albuterol .83 mg/ml solution, Albuterol 90 MCG Inhaler, Cefadroxil 500 MG Capsule, Enalapril Maleate 20 MG Tablet, Isosorbide Mononitrate 60 MG Tablet, Lorazepam 1MG Tablet, Metoprolol 100 MB Tablet and Ranitidine 150 MG Tablet.**

#### Ivax’s Response to Alleged Fact No. 2:

Ivax does not dispute that Ivax’s Albuterol 0.83mg solution, Albuterol 90mcg inhaler, Cefadroxil 500mg capsule, Enalapril Maleate 20mg tablet, Isosorbide Mononitrate 60mg tablet, Lorazepam 1mg tablet, Metoprolol 100mg tablet, and Ranitidine 150mg tablet are drugs at issue in Plaintiffs’ Motion for Partial Summary Judgment.

**PLAINTIFFS' REPLY TO STATEMENT #2:**

No dispute. No further reply is required.

**3. Ivax has entered into and executed the federal Medicaid rebate agreement pursuant to 42 U.S.C. § 1396r-8. See Ivax Corporation's and Ivax Pharmaceutical Corporation's Answer and Affirmative Defenses to the Revised First Amended Complaint ("Ivax Answer") [Dkt #4822] at ¶132.**

Ivax's Response to Alleged Fact No. 3:

Ivax does not dispute that Ivax Pharmaceuticals, Inc. has entered into and executed the federal Medicaid Rebate agreement with the Secretary of Health and Human Services on behalf of all States. However, Ivax disputes that Alleged Fact No. 3 is material to Plaintiffs' Motion for Partial Summary Judgment.

**PLAINTIFFS' REPLY TO STATEMENT #3:**

The parties agree that Ivax Pharmaceuticals, Inc. has entered into and executed the federal Medicaid Rebate agreement with the Secretary of Health and Human Services on behalf of all States. With regard to Ivax Corporation, the Ivax Answer speaks for itself, "Ivax Corp. and IPI admit that they have executed rebate agreements with HHS." Ivax Answer [Dkt# 4822] at ¶132.

This fact is material because Ivax's agreement to this rebate agreement is among the bases for Ivax's obligations to abide by Medicaid's legal requirements, standards and procedures. See *Commonwealth of Mass. v. Mylan*, 2008 WL 5650859 (D.Mass) ("*Mylan*") (citing *Heckler v. Community Health Servs.*, 467 U.S. 51, 63-65, (1984)) at \*25. No further reply is required.

**4. Ivax participates in and is aware of State Medicaid reimbursement formulas, including those of New York State Medicaid Program. See Deposition of Thomas Stuart Blake dated 1/24/08 ("Blake 1/24/08 Dep.") (Exhibit C) at 61:21-62:4; Deposition of Corrine Hogan dated 2/6/08 ("Hogan 2/6/08 Dep.") (Exhibit D) at 68:17-70:9; Deposition of Ivax Corporation 30(b)(6)(Corrine Hogan) dated 6/17/08 ("Ivax 30(b)(6)(Hogan) 6/17/08 Dep.") (Exhibit E) at 36:22-37:19; Exhibit F (Deposition of Trisha Sarfas dated 3/19/09 ("Sarfas 3/19/09 Dep.") Exhibit 3 (April 8, 1999 memo circulating information on each State's reimbursement and substitution program)).**

Ivax's Response to Alleged Fact No. 4:

Disputed. As an initial matter, Ivax disputes Alleged Fact No. 4 to the extent that it permits an inference that Ivax possessed any more or less awareness of reimbursement practices than that which was generally available public knowledge based on the statutory scheme for reimbursement. Ivax does not dispute that it participates in state Medicaid programs, including the New York State Medicaid Program. Ivax disputes that it is “aware of State Medicaid formulas, including those of [the] New York State Medicaid Program” on the grounds that Plaintiffs fail, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence, admissible or otherwise, in support of this statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer “facts that would be admissible in evidence”); *O’Brien*, 440 F. Supp. 2d at 5 n.1. Moreover, Ivax objects to Plaintiffs’ statement on the basis that it lacks adequate foundation. *See* Fed. R. Evid. 602. Indeed, the testimony cited does not support Plaintiffs’ statement. Rather, Mr. Blake testified only that he was generally “aware of Medicaid reimbursement for pharmaceuticals.” Deposition of Thomas Stuart Blake, Jan. 24, 2008 (“1/24/08 Blake Dep.”) at 61:21-62:4 (Ex. 1). Ms. Hogan testified only that she “vaguely” understood how state Medicaid programs work. Deposition of Corrine Hogan, June 17, 2008 (“6/17/08 Hogan Dep.”) at 37:17-19 (Ex. 3). The document cited by Plaintiffs refers only to unspecified “information pertaining to each State’s Medicaid reimbursement and substitution program.” Exhibit 3 to Deposition of Trisha Sarfas, March 19, 2009 (“3/19/09 Sarfas Dep.”) (Ex. 13).

#### **PLAINTIFFS’ REPLY TO STATEMENT #4:**

The parties agree that Ivax participates in state Medicaid programs, including the New York State Medicaid Program.

Ivax cannot reasonably dispute that it knew state Medicaid agencies, including that New York Medicaid, based their reimbursement formulas on WAC, AWP and FUL (or state MAC lists) for Ivax drugs. Ivax’s dispute is baseless. As a matter of law, having entered into the rebate agreements, which Ivax admits (*see* Plaintiffs’ Reply to Statement #3) and voluntarily participates in the New York Medicaid program, Ivax was required to familiarize itself with the legal requirements, standards and procedures of the Medicaid programs, including the reimbursement formulas. *See Mylan*, 2008 WL 5650859 (D.Mass) at \*25 (citing *Heckler v. Community Health Servs.*, 467 U.S. 51, 63-65, (1984)). Moreover, given that New York’s Medicaid pharmacy reimbursement formulas are publicly available, this means Ivax knew, for

example, that New York Medicaid reimbursed on the FUL when a FUL was in place and that New York also reimbursed on the basis of AWP minus a percentage.

Responding further, Ivax's dispute that the Statement permits an inference that "Ivax possessed any more or less awareness of reimbursement practices than that which was generally available public knowledge based on the statutory scheme for reimbursement" is also baseless. New York's reimbursement scheme is statutorily defined and publically available.

Ivax's dispute that plaintiffs have not proffered adequate evidence to support the statement that Ivax was "aware of State Medicaid formulas, including those of [the] New York State Medicaid Program" is baseless. The cited testimony speaks for itself:

Q. And in the course of your responsibilities at IVAX, did you need to be **aware** of Medicaid reimbursement for pharmaceuticals?

MS. LEVY: Objection to form.

You can answer.

THE WITNESS: Yes.

Blake 1/24/08 Dep.")(Exhibit C) at 61:21-62:4 (emphasis added).

**5. Ivax knew that eligibility for reimbursement by Medicaid was an important issue for its customers. See Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 36:4-14; Bloom 2/4/09 Dep. (Exhibit B) at 24:5-16.**

Ivax's Response to Alleged Fact No. 5:

Disputed. Ivax disputes that Alleged Fact No. 5 is material to Plaintiffs' Motion for Partial Summary Judgment. Further, Ivax disputes that it "knew that eligibility for reimbursement by Medicaid was an important issue for its customers" on the grounds that Plaintiffs fail, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence, admissible or otherwise, in support of this statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer "facts that would be admissible in evidence"); *O'Brien*, 440 F. Supp. 2d at 5 n.1. Indeed, the testimony cited does not support Plaintiffs' statement. Ms. Hogan's testimony does not relate at all to this alleged fact. Ms. Bloom testified only that Ivax's "customers are very concerned about their reimbursement." Deposition of Kim Bloom, Feb. 4, 2009 ("2/4/09 Bloom Dep.") at 24:9-11 (Ex. 4). Moreover, Ivax objects to Plaintiffs' statement on the basis that it lacks adequate foundation. *See* Fed. R. Evid. 602.

**PLAINTIFFS' REPLY TO STATEMENT #5:**

The parties agree that Ivax's customers are very concerned about their reimbursement. Responding further, the record evidence is that "Ivax knew that eligibility for reimbursement by Medicaid was an important issue for its customers."

Ivax's dispute is baseless. Ivax's 30(b)(6) witness's testimony is as follows:

Q. IVAX is not required -- was not required to participate in a Medicaid program, was it, as far as you know?

MR. BRYAN: Object to form.

THE WITNESS: I think that our customers would say that we were required to participate in it, yes.

BY MR. BARNHILL:

Q. So IVAX would participate because it needs to sell drugs to its customers?

A. Yes.

Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 36:4-14

**6. Corrine Hogan testified, "I think that our customers would say that we were required to participate in [Medicaid], yes." See Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 36:8-10.**

Ivax's Response to Alleged Fact No. 6:

Ivax does not dispute Alleged Fact No. 6. Ivax disputes any suggestion that it was, in fact, required to participate in Medicaid. Regardless, this alleged fact is immaterial to Plaintiffs' Motion for Partial Summary Judgment.

**PLAINTIFFS' REPLY TO STATEMENT #6:**

The parties agree that Ivax voluntarily participated in Medicaid. No further reply is required.

**7. Ivax knew that AWP and WAC were used for state Medicaid reimbursement purposes. See Bloom 2/4/09 Dep. (Exhibit B) at 69:10-70:6. Kim Bloom testified that it was important to have Ivax products approved for Medicaid because "[a] pharmacy is not going to use your product if they're not going to be reimbursed." Id. at 71:1-8.**

Ivax's Response to Alleged Fact No. 7:

Disputed. Ivax disputes that Alleged Fact No. 7 is material to Plaintiffs' Motion for Partial Summary Judgment. Further, Ivax disputes Alleged Fact No. 7 to the extent that it permits an inference that Ivax possessed any more or less awareness of reimbursement practices than that which was generally available public knowledge based on the statutory scheme for reimbursement. To the extent that Alleged Fact No. 7 purports to suggest that the reason Ivax reported pricing information was so that pharmacists could be paid by third party payors, Ivax objects.

Furthermore, Ivax objects to Alleged Fact No. 7 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP's in setting FULs. *See* Deposition of Sue Gaston, March 19, 2008 ("3/19/08 Gaston Dep.") at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005) (refusing to consider immaterial facts as part of a motion for summary judgment).

#### **PLAINTIFFS' REPLY TO STATEMENT #7:**

Ivax does not dispute that it knew that WAC and AWP were used for Medicaid reimbursement purposes. Ivax disputes only the materiality of the Statement and an alleged inference.

Ivax's dispute concerning an alleged inference about the scope of Ivax's knowledge of the use of AWP and WAC for reimbursement purposes is specious. *See* Plaintiffs' Reply to Statement #4, which is incorporated herein.

Plaintiffs further designate the testimony of Kim Bloom:

Q I want to clear up something that we talked about earlier. I think we talked about this, but I want to make sure.

When IVAX sent AWP's and WAC's to the pricing compendia, it was aware that those numbers were being used for Medicaid reimbursement and other reimbursements?

A No, they were sent to the compendia because we were supposed to and because that's how customers downloaded the information into their systems. But that wasn't the primary reason of why pricing was sent



to those offices.

Q But was there an awareness that that was one of the uses of the information?

A Sure.

Bloom 2/4/09 Dep. (Exhibit B) at 156:6-23

Responding further, Ivax's Response that AWP prices are not material to plaintiffs' motion is incorrect. In setting the FUL, CMS considered the published prices from First Databank, Red Book and Medi-Span that were presented in the FULs printouts. *See* Gaston Decl. at ¶3 (statement of general practice). This included AWP, WACs and Direct Prices. *See id.* at Exhibits A & D (FULs system printouts showing AWP prices). Defendants admit that the published prices presented in the FULs printouts included AWP. *See* Defendants' Response to Plaintiffs' Local Rule 56.1 Statement of "Undisputed" Facts Applicable To All Defendants and Statement of Additional Undisputed Material Facts [Dkt#:6117] ("Def. Common Response") at ¶9.

The remainder of Ivax's Response is disputed and irrelevant.

***Ivax Set and Reported Its AWP and WACs***

**8. At all times, from 1997 to 2005, at the time of launch of a new product Ivax set an AWP and a WAC for each of its drugs as well as the pricing "buckets" for each of its customers. *See* Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 56:17-57:21.**

**Ivax's Response to Alleged Fact No. 8:**

Disputed in part. Ivax disputes Alleged Fact No. 8 because it misstates, mischaracterizes, and/or misconstrues the cited deposition testimony. Ms. Hogan testified only that between 1997 and 2003, when Ivax was "exclusive," it set an AWP, a WAC, and pricing "buckets" for different customer types. 6/17/08 Hogan Dep. at 56:12-57:21 (emphasis added) (Ex. 3). Accordingly, Ivax disputes that "[a]t all times, from 1997 to 2005, at the time of launch of a new product[,] Ivax set an AWP and a WAC for each of its drugs as well as the pricing 'buckets' for each of its customers" on the grounds that Plaintiffs fail, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence, admissible or otherwise, in support of this statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer "facts that would be admissible in evidence"); *O'Brien*, 440 F. Supp. 2d at 5 n.1. Moreover, Ivax objects to



Plaintiffs' statement on the basis that it lacks adequate foundation. *See* Fed. R. Evid. 602.

Furthermore, Ivax objects to Alleged Fact No. 8 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

#### **PLAINTIFFS' REPLY TO STATEMENT #8:**

The Parties agree that between 1997 and 2003, when Ivax was "exclusive," it set an AWP, a WAC, and pricing "buckets" for different customer types. As for the period for 2004-2005 and/or instances when Ivax was not "exclusive", Ivax cannot reasonable dispute that it sets an AWP and WAC for each of its drugs. *See* Plaintiffs' Replies to Statement #9, #11 and #12, which are incorporated herein.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**9. Ivax's standard practice was to set the AWP for its drugs at 89.5% of the brand AWP as published by First Databank to obtain the generic drug indicator and be deemed a generic. Deposition of Ivax Corporation 30(b)(6)(Trisha Sarfas) dated 8/22/07 ("Ivax 30(b)(6)(Sarfas) 8/22/07 Dep.") (Exhibit G) at 154:11-155:11. Ivax admits that it would have been deemed a generic if its AWP had been at 75% of the brand AWP the drug would still have been deemed a generic. *Id.* at 155:13-20.**

Ivax's Response to Alleged Fact No. 9: Disputed. While Ivax does not dispute that, in general, Ivax's AWP were approximately 89.5% of the equivalent brand's AWP, Ivax objects to Alleged Fact No. 9 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a

situation where they did.”) (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs’ Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

Ivax further objects to Alleged Fact No. 9 to the extent that it is misleading and mischaracterizes the evidence. Plaintiffs’ statement incorrectly implies that manufacturers, and not First DataBank, are in control of populating the AWP field in the database. *See* Deposition of Patricia Kay Morgan, Nov. 30, 2007 (“11/30/07 Morgan Dep.”) at 33:1-5 (“Q. During the period when you were employed by First DataBank, the manufacturer did not decide whether First DataBank used the suggested AWP as its Blue Book AWP, correct? A. That’s correct.”) (Ex. 6); *id.* at 33:6-10 (“Q. During the time period when you were employed by First DataBank, manufacturers did not control the methodology used by First DataBank in populating its Blue Book AWP fields, correct? . . . A. That’s correct.”) (Ex. 6); *id.* at 33:11-20 (“Q. During the time period you were employed by First DataBank, manufacturers did not set the AWP’s listed in First DataBank’s Blue Book AWP fields, correct? . . . A. That’s correct.”) (Ex. 6).

In addition, First DataBank would run a statistical analysis, utilizing an algorithm, and if that product fell within a single standard deviation of where other competitors in the marketplace were setting their AWP’s, it was coded a generic. *See id.* at 149 (“The computer determines the most common package size for the products that are in a GCN. . . . It then determines the mean of the AWP for those most common package size. It does a standard deviation of . . . that mean, and excludes any product that is more than one standard deviation above that mean or more than one standard deviation below that mean.”) (Ex. 6). Accordingly, adjustments needed to be made when competitors’ prices changed in the marketplace. After the product was launched, then Ivax did not typically or usually suggest an increase for its AWP, even if the brand had done so. *See* Deposition of Corrine Hogan, Feb. 6, 2008 (“2/6/08 Hogan Dep.”) at 149 (Ex. 12).

Ivax also disputes Plaintiffs’ statement insofar as it implies that it was Ivax, rather than First DataBank, that established the protocols on how the AWP’s of secondary and subsequent generic market entrants were established. In particular, Ivax’s witnesses testified that upon launching a generic pharmaceutical product, Ivax would provide First DataBank with its suggested AWP which would be set at slightly more than 10% off the brand AWP. *See, e.g., id.* at 147 (Ex. 12); Deposition of Robert Shanks, Feb. 22, 2008 (“2/22/08 Shanks Dep.”) at 48-49 (“[W]hen you went to market [with a drug] you had to be listed in the pricing services, you know, like First Data Bank. They required . . . you . . . to be in there because if you didn’t have your [AWP] number in there when people submitted bid proposals, [you would not be able to sell your product.] . . . And in order to be listed as a generic, they required your AWP be at least ten percent lower than the brand.”) (Ex. 7). Ivax did so because decisions regarding the setting of AWP were guided primarily by the rules established by First DataBank—rules which predetermined the allowable price ranges to maintain a generic coding. *See* 2/6/08 Hogan Dep. at 147 (Ex. 12); 2/22/08 Shanks Dep. at

48-49 (Ex. 7); 11/30/07 Morgan Dep. at 33, 149 (Ex. 6). Ivax further disputes Plaintiffs' statement in that it overly simplifies the protocols established by First DataBank, as AWP was set on a case-by-case basis, after thorough consideration of a variety of issues (including consideration of what was required by First DataBank to achieve the generic indicator), all of which existed within the heartland of the protocols established by First DataBank. *See* Deposition of Trisha Sarfas, Aug. 22, 2007 ("8/22/07 Sarfas Dep.") at 148, 323 (Ex. 11).

**PLAINTIFFS' REPLY TO STATEMENT #9:**

The parties agree that, in general, Ivax set its AWP at approximately 89.5% of the equivalent brand's AWP. Ivax does not dispute that it sets an AWP for its drugs, nor does Ivax dispute that it set its AWP in order to obtain the generic drug indicator and be deemed a generic. Ivax admits it provided its AWP to the publishing compendia.

Responding further, the cited record evidence clearly supports the Statement:

Q. .... And I think you said, and you correct me if I'm wrong, that typically usually the practice was to establish the launch AWP at 89.5 percent of the brand; is that right?

A. Yes.

Q. And I think you said the reason for doing that was you had to report a price in order to get established and that you wanted to be designated as a generic; is that right?

A. Correct.

Q. And was it Ivax's understanding that you had to be more than 10 percent below the brand AWP for FirstData Bank to classify you as a generic product?

A. Yes, that was Ivax's understanding.

Q. All right.

So, you were coming just under the threshold, that additional .5 percent, right?

A. Correct.

Q. And was that pretty much the rule of thumb throughout the time that you were the Manager of the Contracts Department?

A. Yes, this was our standard practice.

Q. Okay.

Now, if you had reported a price that was 85 percent of the brand's AWP you would have

been designated as a generic; correct?

A. Yes, but our --

Q. And if you had reported a price that was 75 percent to brand AWP you would have been a generic, right?

A. Yes.

Ivax 30(b)(6)(Sarfes) 8/22/07 Dep. (Exhibit G) at 154:11-155:20.

Ivax's objection to Plaintiffs' statement that it is misleading and mischaracterizes the evidence because it "incorrectly implies that manufacturers, and not First DataBank, are in control of populating the AWP field in the database" is incorrect. Ivax cannot reasonably object that it set its AWP and provided its AWP to the pricing compendia. *See* Plaintiffs' Replies to Statements #8 and #14. Ivax also monitored the AWP published by the pricing compendia for accuracy. *See* Plaintiffs' Reply to Statement #12, #14, #15, #16 and #17, which are incorporated herein. Ivax's argument regarding First Data Bank is improper in the context of a 56.1 and contrary to the rulings of the Court. *See Mylan*, 2008 WL 5650859 (D.Mass) at \*4.

Responding further, plaintiffs dispute and object to the use and citation of the 11/30/07 Deposition of Patricia Kay Morgan. The deposition was noticed in the *Commonwealth of Massachusetts v. Mylan* case, which is neither the NY Counties case nor part of MDL 1456. Moreover, the deposition was neither noticed nor cross-noticed in the New York Counties case nor any other case in MDL 1456. Thus, the NY County plaintiffs had no opportunity to examine Ms. Morgan in connection with her November 30, 2007 testimony. Nor has there been any agreement between the parties that the 11/30/07 Morgan transcript could be used in this case. The 11/30/07 transcript therefore is inadmissible hearsay that cannot be relied upon properly in the context of a Rule 56 motion. *See* Fed.R.Civ.P. 56(e)(1) (requiring moving party to proffer "facts that would be admissible in evidence"); *O'Brien v. Town of Agwam*, 440 F. Supp.2d 3, 5, n.1 (D. Mass. 2006). Moreover, plaintiffs object to the Statement insofar it lacks foundation. *See*

Fed.R.Evid. 602. The exclusion of this improper transcript is all the more appropriate given that Ms. Morgan was deposed in the instant case for three full days (January 11 & 12, 2005 and August 27, 2007) and defendants certainly could have elicited the favored testimony during that time. They did not. Last, it is indisputable that the Court has conclusively addressed First Databanks' role in these matters and has consistently found (including in *Mass. v. Mylan*, the venue case of the improper Morgan testimony), that defendants provide and control their published AWP's and WAC's. *See Mylan*, 2008 WL 5650859 (D.Mass) at \*4 ("The defendants, like all manufacturers, supply their AWP's and WAC's to third party publishers which publish pricing lists organized by drug. [...] Some defendants did not report WAC's to FDB for certain drugs; FDB, in turn, would not publish a WAC for that drug."); *see also In re Pharm Indus Average Wholesale Price Litig.* 252 F.R.D. 83 (D.Mass 2008); *In re Pharm Indus Average Wholesale Price Litig.* 478 F Supp. 2d 164, 170 (D Mass 2007); *see also Inola Drug, Inc. v. Express Scripts, Inc.*, 2009 WL 801838 (N.D.Okla., March 25, 2009) at \*1 (recognizing that manufacturers control AWP's and pricing services like First Databank, Medi-Span and Redbook publish them).

Ivax's response concerning how the AWP's of secondary and subsequent generic market entrants were established is irrelevant to this Statement and requires no response.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**10. While Ivax wanted to be deemed a generic, it also wanted to be in line with the competition. *See* Sarfas 3/19/09 Dep. (Exhibit H) at 65:5-13. If the competition was at 50% below the brand AWP, then Ivax would set its AWP to be comparable. *Id.* at 66:7-11.**

Ivax's Response to Alleged Fact No. 10:

Disputed. Ivax objects to Alleged Fact No. 10 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. See 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. See D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

Ivax disputes that it "wanted to be deemed a generic, [and] it also wanted to be in line with the competition" on the grounds that Plaintiffs fail, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence, admissible or otherwise, in support of this statement. See Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer "facts that would be admissible in evidence"); *O'Brien*, 440 F. Supp. 2d at 5 n.1. Moreover, Ivax objects to Plaintiffs' statement on the basis that it lacks adequate foundation. See Fed. R. Evid. 602. Furthermore, this alleged fact is not properly supported by the testimony cited. Ms. Sarfas testified only that in determining pricing, "[t]he important thing is that my pricing across the spectrum is comparable to the competition." 3/19/09 Sarfas Dep. at 65:5-13 (Ex. 9).

#### **PLAINTIFFS' REPLY TO STATEMENT #10:**

Ivax does not dispute the statement, but argues that plaintiffs did not provide evidentiary support. The cited testimony clearly supports the statement and speaks for itself as follows:

Q. [...] Isn't it true that in order to achieve a generic price indicator as a generic, IVAX could have set its AWP's at like, for instance, 20 percent off of the -- 20 percent off or 80 percent off the brand AWP?

A. The important thing is that my pricing across the spectrum is comparable to the competition. So if the competition falls that way or basically wherever which way they are going to go, that's where I'm going to try to stay in suit with.

Sarfas 3/19/09 Dep. (Exhibit H) at 65:5-13

Q. (BY MR. ANDERSON) Right. But, for instance, if the competition -- it's your testimony that if the competition was at 50 percent off of brand AWP, then IVAX would be at 50 percent, right?

A. We would be comparable, yes.

*Id.* at 66:7-11.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**11. Ivax sets its WAC when it is the first generic manufacturer to enter the market as a function of the published brand WAC, typically around 30-35% below the published brand WAC. *See* Hogan 2/6/08 Dep. (Exhibit D) at 91:3-13; Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 68:7-19.**

Ivax's Response to Alleged Fact No. 11:

Disputed. As an initial matter, Ivax objects to Alleged Fact No. 11 to the extent that it is misleading and mischaracterizes the evidence. Plaintiffs' statement incorrectly purports to state the universe of policies regarding how WACs were ascertained for Ivax's products during the relevant time period. For example, Ivax witnesses have testified that with regard to Clozapine, its WAC (also called WIP, or Wholesaler Invoice Price) was set at 16.67 percent below the brand's direct price, and not Plaintiffs' alleged universal 30 to 35 percent below the brand's WAC. *See* Exhibit 11 to 2/22/08 Shanks Dep. (Ex. 8); 2/22/08 Shanks Dep. at 153-160 (Ex. 7). Accordingly, Ivax disputes Alleged Fact No. 11.

**PLAINTIFFS' REPLY TO STATEMENT #11:**

Ivax does not dispute that it sets a WAC when it is the first generic manufacturer to enter the market. Ivax does not dispute that it sets its WACs in relation to the published brand WAC. Ivax's dispute that the Statement "purports to state the universe of policies regarding how WAC were ascertained for Ivax's products" is belied by the Statement itself which expressly says that it is describing practices "when it is the first generic manufacturer to enter the market" and "typically". *See also* Plaintiffs' Reply to Statement #12, which is incorporated herein.

In any event, the cited record evidence supports the Statement and is as follows:

Q. And with regard to the establishment of the WAC price at launch, what was the practice at IVAX during the relevant time period?

A. And again, it depends on the product and if you have competition or you don't have competition.



Q. And in those circumstances where IVAX had an exclusive, what was the practice with regard to the establishment of a WAC at launch?

A. It would be 30 to 35 percent off of the brand published WAC.

Hogan 2/6/08 Dep. (Exhibit D) at 91:3-13

Q. But was there any other relationship between WAC and the real price?

MR. BRYAN: Objection to form.

THE WITNESS: The real price, you mean, the contract price?

BY MR. BARNHILL:

Q. Yeah, the contract price.

A. Initially WAC, again, was a function of the brand when you initially launched. As time goes on, WAC becomes a competitive price. You saw published prices from all of your competitors, and you couldn't be a whole heck of a lot higher or a whole heck of a lot lower.

Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 68:7-19

Plaintiffs do not dispute that in the example cited by Ivax in its response, the WAC was set at 16.67 percentage of the brand WAC. The salient point is that Ivax sets WACs for its products and when Ivax is the first generic manufacturer to enter the market it sets the WAC as a percentage of the brand WAC.

**12. Ivax would often set its Premier Retail Price to chain pharmacies at 50% of the published brand WAC, then establish its customer “pricing buckets” upward and finally setting its WAC above all the customer “pricing buckets”. See Bloom 2/4/09 Dep. (Exhibit B) at 43:19-46:7. If Ivax was not the first to enter the market and competition existed then it was Ivax practice to set its WAC as low as competitively possible but in line with the published WACs of the competition. See Hogan 2/6/08 Dep (Exhibit D) at 91:14-18; Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 68:14-19.**

Ivax’s Response to Alleged Fact No. 12:

Disputed. As an initial matter, Ivax objects to Alleged Fact No. 12 to the extent that it is misleading and mischaracterizes the evidence. Plaintiffs’ statement incorrectly purports to state the universe of policies regarding how WACs were ascertained for Ivax’s products during the relevant time period and other pricing was determined. Accordingly, Ivax disputes Alleged Fact No. 12.

**PLAINTIFFS' REPLY TO STATEMENT #12:**

Ivax does not dispute that it sets its Premier Retail Price to chain pharmacies and other “pricing buckets” as a function of the published brand WAC. Nor does Ivax dispute that when it was not the first to enter the market and competition existed then it was Ivax practice to set its WAC as low as competitively possible but in line with the published WACs of the competition. Ivax’s dispute of the Statement on the grounds that it purports to state the universe of policies regarding how WACs were set by Ivax is belied by the language of Statement itself which expressly states that it concerns occasions when “Ivax was not the first to enter the market” and describes a practice that Ivax “often”, not “always” employed. *See also* Plaintiffs’ Reply to Statement #11, which is incorporated herein. Responding further, the cited testimony of Ms. Bloom and Ms. Hogan clearly support the Statement as follows:

A. [...] We would probably start with our premier retail pricing and primarily to be considered generic to a chain, you would want to be 50 percent of the brand.

Q. Fifty percent of the brand?

A. Prices.

Q. AWP, WAC?

A. WAC. And we would start there and then we would work up to the other buckets. AWP was established at 90 percent of the brand AWP, if you're single source, so that you can be considered generic. And then you had -- all the other functions, you would start from the bottom and work your way up.

Q. So you'd start out -- generally, the premier retail price would be 50 percent of the brand WAC, the comparable brand WAC?

A. Correct.

Q. And then how would you proceed to build on that?

A. You would -- if I can remember correctly, we would take certain percentages. I can't tell you what those percentages are. I'm going back too far there, but there were certain percentages that we would

go up.

Q. And then, say, the top price would be - the top contract price would be NCG?

A. Yes.

Q. You got a sense for what that range would be between premier retail and NCG? NCG would be, for example, twice premier?

A. I would say 20 percent higher.

Q. Twenty percent higher?

A. Yes.

Q. And then --

A. You might even -- if you are single source, you might have your managed health care, your CBG, and your NCG all at the same price because there would be no real reason to have a differentiation between them.

Q. And then you would have your distributor cost at premier retail plus a percentage?

A. We would probably set that based on our CBG price down, so maybe 10 percent below whatever our retail price ended up to be.

Q. And then how about your WAC?

A. WAC would be a function of, at that point, in a single source, a function of what your retail price would be to generate a charge-back. It might be five, ten percent above what you established your retail price to be.

Bloom 2/4/09 Dep. (Exhibit B) at 43:19-46:7

Q. And if you had other generic competitors at the time IVAX was launching, what would the practice -- what was the practice?

A. As low as I could go with remaining competitive.

Hogan 2/6/08 Dep (Exhibit D) at 91:14-18 (discussing WAC)

A. Initially WAC, again, was a function of the brand when you initially launched. As time goes on, WAC becomes a competitive price. You saw published prices from all of your competitors, and you couldn't be a whole heck of a lot higher or a whole heck of a lot lower.

Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 68:14-19

Notably, Ivax does not dispute that Ms. Bloom's and Ms. Hogan's testimony supports the Statement. No further reply is required.

**13. In addition to the AWP and WAC "pricing buckets", Ivax maintained "pricing buckets" for each of its customer types: Distributor, Premier Retail (chains), Retail (independent pharmacies), Compliant Buying Group (retail GPOs), Non-Compliant Buying Group (retail pharmacies), Managed Health Care (institutional/hospital), and Government (Prisons, Federal Supply Schedule). See Bloom 2/4/09 Dep. (Exhibit B) at 36:15-42:3. All customer "pricing buckets" were below the WAC with Premier Retail (chains) being the best price offered by Ivax, and the WAC was below the AWP. *Id.* at 42:8-43:14. The Premier Retail (chains) and the Distributor "pricing buckets" are net prices, while the others are contract prices. *Id.* at 49:23-51:8.**

Ivax's Response to Alleged Fact No. 13:

Disputed. Ivax disputes Alleged Fact No. 13 on the grounds that Plaintiffs have cited no evidentiary basis for this alleged fact, as is required by Local Rule 56.1. See O'Brien, 440 F. Supp. 2d 3, 5 n.1. In particular, Ivax disputes that it maintained "AWP and WAC 'pricing buckets.'" Ivax also disputes that it "maintained 'pricing buckets' for each of its customer types," that the Compliant Buying Group consisted of retail GPOs, and that the Non-Compliant Buying Group consisted of retail pharmacies. Plaintiffs have not provided any evidentiary basis for these assertions, as is required by Local Rule 56.1. *O'Brien*, 440 F. Supp. 2d at 5 n.1.

Further, Ivax objects to Alleged Fact No. 13 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. See 3/19/08 Gaston Dep. at 457:21- 458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. See D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

**PLAINTIFFS' REPLY TO STATEMENT #13:**

The parties agree that Ivax maintained "pricing buckets" for customers. See Plaintiffs' Reply to Statement #12, which is incorporated herein.

Responding further, Ivax disputes that "the Compliant Buying Group consisted of retail GPOs, and that the Non-Compliant Buying Group consisted of retail pharmacies." This dispute is contradicted by the record evidence. Ms. Bloom clearly testified:

Q Any other pricing buckets?

A I don't think so.

Q There's one that I've seen in some of the documents called CBG?

A That's compliant buying group.

Q Yes.

A That's tied to retail pricing. It might be a little bit better, depending on the market. It might be for a big GPO of retail independent stores where we felt that they were compliant to their contract.

You have to understand that a lot of these members out there belong to multiple memberships and really drive no compliance to the contract, so if we felt that this buying group had a large presence and their members were compliant, we might give them a little better prices.

Q I see, if they agree to be true to IVAX, huh?

A You got it.

Q Would there be a noncompliant buying group?

A Yes, there was an NCG.

Q NCG?

A Yes, which was retail.

Q That's the retail price?

A Yes.

Q Does that stand for something, NCG?

A Noncompliant group.

Bloom 2/4/09 Dep. (Exhibit B) at 40:23-41:24.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**14. At all times, from 1997 to 2005, Ivax reported both AWP and WAC for its drugs to all three of the national compendia – First DataBank, RedBook and Medi-Span. *Id.* at 74:22-76:2; 156:9-20; Ivax 30(b)(6)(Sarfes) 8/22/07 Dep. (Exhibit G) at 127:1-9, 322:1-323:16, 327:22-328:2-6; *see also* *Commonwealth of Mass. v. Mylan*, 2008 WL 5650859 (D.Mass) (“*Mylan*”) at \*6.**

Ivax's Response to Alleged Fact No. 14:

Disputed. While Ivax does not dispute that at times Ivax provided AWPs and WACs for its drugs to First DataBank, Ivax disputes that it reported AWPs and WACs for its drugs to the pricing compendia “[a]t all times, from 1997 to

2005,” and Plaintiffs have not provided any evidentiary basis for this assertion, as is required by Local Rule 56.1. *O’Brien*, 440 F. Supp. 2d at 5 n.1.

Further, Ivax disputes Alleged Fact No. 14 because the deposition testimony it cites provides an insufficient evidentiary basis in support of these alleged facts. In particular, the complete testimony of Ivax’s witnesses explains that while Ivax did provide First DataBank with its WACs and AWP, it did so because these pricing points were a prerequisite for its products to receive First DataBank’s generic indicator, and thus be selected by customers and dispensed by providers. See 8/22/07 Sarfas Dep. at 148-149, 323 (Ex. 11). WAC is understood in the industry to represent an invoice price off of which chargebacks and rebates to retailers or wholesalers are calculated. See, e.g., 42 U.S.C. § 1395w-3a(c)(6)(B) (providing that the “term ‘wholesale acquisition cost’ means, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, . . . as reported in wholesale price guides or other publications of drug or biological pricing data.”) (emphasis added). First DataBank collected AWP and WAC pricing information because its entire business model was premised on providing an electronic resource for pricing points to its customers. See 8/22/07 Sarfas Dep. at 147 (Ex. 11). Accordingly, Ivax disputes Plaintiffs’ statements to the extent that they omit these reasons for which Ivax provided WACs and AWP to First DataBank for the subject drugs sold by Ivax during the relevant time period. See *id.* at 253 (Ex. 11).

Ivax objects to Alleged Fact No. 14 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs’ Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. See 3/19/08 Gaston Dep. at 457:21-458:7 (“Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can’t think of a situation where they did.”) (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs’ Motion for Partial Summary Judgment. See D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

Moreover, Ivax disputes Plaintiffs’ statements insofar as they misstate, mischaracterize and/or misunderstand the manner in which First DataBank populates its AWP field. See, e.g., 11/30/07 Morgan Dep. at 17-18, 19, 27-29, 31-33 (Ex. 6). First DataBank populates its BlueBook AWP with numbers based on surveys of wholesalers. See *id.* at 32 (“Q. Based on First DataBank’s definition, AWP is a price based on information from the wholesaler, not the manufacturer, correct? A. That’s correct.”) (Ex. 6). Further, Ivax disputes Plaintiffs’ statements to the extent that they incorrectly imply that manufacturers, and not First DataBank, are in control of populating the AWP field in the database. *Id.* at 33 (“Q. During the period when you were employed by First DataBank, the manufacturer did not decide whether First DataBank used the suggested AWP as its Blue Book AWP, correct? A. That’s correct.”) (Ex. 6); *id.* (“Q. During the time period when you were employed by First DataBank, manufacturers did not control the methodology used by First DataBank in populating its Blue Book

AWP fields, correct? . . . A. That's correct.") (Ex. 6); *id.* ("Q. During the time period you were employed by First DataBank, manufacturers did not set the AWP fields listed in First DataBank's Blue Book AWP fields, correct? . . . A. That's correct.") (Ex. 6).

Ivax further objects to Plaintiffs' statements in that Plaintiff fails, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any admissible evidence in support thereof. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer "facts that would be admissible in evidence"); *O'Brien*, 440 F. Supp. 2d at 5 n.1. Moreover, Ivax objects to Plaintiffs' statements because they lack adequate foundation. *See* Fed. R. Evid. 602. In addition, Ivax disputes Plaintiffs' Statement insofar as it represents that Ivax "reported" any prices to First DataBank or any other entity.

#### PLAINTIFFS' REPLY TO STATEMENT #14:

The parties agree that Ivax provided its WACs and AWP fields to First Databank.

Ivax's dispute that "it reported AWP fields and WACs for its drugs to the pricing compendia '[a]t all times, from 1997 to 2005'" is baseless and not made in good faith. Ivax 30(b)(6) designee unequivocally testified that in 2007 that Ivax's Product Bulletin was sent to all three compendia (*see* Ivax 30(b)(6)(Sarfes) 8/22/07 Dep. (Exhibit G) at 127:1-9), and contained AWP and WAC prices (*id.* at 322:1-323:16). The Ivax designee further testified that Ivax had been providing Product Bulletins "ever since [Ivax has] been in business" (*id.* at 327:22-328:6), which includes 1997 to 2005.

Responding further, Ivax's dispute that it "reported" any prices is specious and not made in good faith, Ms. Sarfes testified:

Q. Okay.

I want to focus on AWP first. Did Ivax **report** AWP prices to any price reporting services?

A. Yes.

Q. All right.

What service did with you **report** AWP fields for?

A. FirstData Bank, Medispan, Red Book.

30(b)(6)(Sarfes) 8/22/07 Dep. at 145:15-146:1(emphasis added).



Responding further, Ivax's dispute to the Statement to the extent that it does not include the reasons Ivax reported AWP's and WAC's is irrelevant to the Statement and baseless. *See* Plaintiffs' Reply to Statement #9, which is incorporated herein.

Ivax's responses concerning industry understandings of WAC are irrelevant to the statement and disputed for, *inter alia*, the reasons set forth in Plaintiffs' Memorandum of Law In Support of Motion For Partial Summary Judgment On Issue Relating To The Federal Upper Limit and Under New York Social Services Law §145-B ("Plaintiffs' PSJ Mem.") [Dxt#: 6077] and Plaintiffs' Memorandum of Law in Opposition to Defendants' Joint Motion For Summary Judgment On Plaintiffs' "FUL Fraud" Claims And In Further Support of Plaintiffs' Motion of Partial Summary Judgment On Their §145-B Claims ("Plaintiffs' SJ Opp.") [Dkt#: 6147], which are incorporated herein.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

Responding further, Ivax's argument that FDB, rather than Ivax, determined how Ivax's AWP's were set and controlled is belied by the cited record evidence (*see* Plaintiffs' Replies to Statement #14, #15, #16 and #17, which are incorporated herein), Ivax's own admissions (*see* Ivax's response to Statement # 8, which is incorporated herein) and contrary to the rulings of the Court. *See* Plaintiffs' Reply to Statement #9.

Responding further, plaintiffs object to and dispute the use of the 11/30/07 Deposition of Kay Morgan. *See* Plaintiffs' Reply to Statement #9, which is incorporated herein.

**15. Ivax knew and controlled the AWP's and WAC's for its drugs that were published by the national drug pricing compendia knowing that its WAC's and AWP's would then be used by state Medicaid agencies. *See* Sarfas 3/19/09 Dep. (Exhibit H) at**

**31:22-32:4, 35:20-25; 37:18-38:1, 193:18-24; 195:12-196:9; Bloom 2/4/09 Dep. (Exhibit B) at 74:22-76:2; 156:9-20.**

Ivax's Response to Alleged Fact No. 15:

Disputed. As an initial matter, Ivax objects to Alleged Fact No. 15 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. See 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. See D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

Ivax objects to Alleged Fact No. 15 to the extent that it is misleading and mischaracterizes the evidence. Plaintiffs' statement incorrectly implies that manufacturers, and not First DataBank, are in control of populating the AWP field in the database. See 11/30/07 Morgan Dep. at 33 ("Q. During the period when you were employed by First DataBank, the manufacturer did not decide whether First DataBank used the suggested AWP as its Blue Book AWP, correct? A. That's correct.") (Ex. 6); *id.* ("Q. During the time period when you were employed by First DataBank, manufacturers did not control the methodology used by First DataBank in populating its Blue Book AWP fields, correct? . . . A. That's correct.") (Ex. 6); *id.* ("Q. During the time period you were employed by First DataBank, manufacturers did not set the AWP listed in First DataBank's Blue Book AWP fields, correct? . . . A. That's correct.") (Ex. 6).

In addition, First DataBank would run a statistical analysis, utilizing an algorithm, and if that product fell within a single standard deviation of where other competitors in the marketplace were setting their AWP, it was coded a generic. See *id.* at 149 ("The computer determines the most common package size for the products that are in a GCN. . . . It then determines the mean of the AWP for those most common package size. It does a standard deviation of . . . that mean, and excludes any product that is more than one standard deviation above that mean or more than one standard deviation below that mean.") (Ex. 6). Accordingly, adjustments needed to be made when competitors' prices changed in the marketplace. After the product was launched, then Ivax did not typically or usually suggest an increase for its AWP, even if the brand had done so. See 2/6/08 Hogan Dep. at 149 (Ex. 12).

Ivax also disputes Plaintiffs' statement insofar as it implies that it was Ivax, rather than First DataBank, that established the protocols on how the AWP of secondary and subsequent generic market entrants were established. In particular, Ivax's witnesses testified that upon launching a generic pharmaceutical product, Ivax would provide First DataBank with its suggested AWP which would be set at slightly more than 10 percent off the brand AWP. See, e.g., 2/6/08 Hogan Dep. at 147 (Ex. 12); 2/22/08 Shanks Dep. at 48-49 ("[W]hen you went to

market [with a drug] you had to be listed in the pricing services, you know, like First Data Bank. They required . . . you . . . to be in there because if you didn't have your [AWP] number in there when people submitted bid proposals, [you would not be able to sell your product.] . . . And in order to be listed as a generic, they required your AWP be at least ten percent lower than the brand.") (Ex. 7). Ivax did so because decisions regarding the setting of AWP were guided primarily by the rules established by First DataBank—rules which predetermined the allowable price ranges to maintain a generic coding. *See* 2/6/08 Hogan Dep. at 147 (Ex. 12); 2/22/08 Shanks Dep. at 48-49 (Ex. 7); 11/30/07 Morgan Dep. at 33, 149 (Ex. 6). Ivax further disputes Plaintiffs' statement in that it overly simplifies the protocols established by First DataBank, as AWP was set on a case-by-case basis, after thorough consideration of a variety of issues (including consideration of what was required by First DataBank to achieve the generic indicator), all of which existed within the heartland of the protocols established by First DataBank. *See* 8/22/07 Sarfas Dep. at 148, 323 (Ex. 11).

Furthermore, Ivax disputes that it "knew and controlled the AWP's and WAC's for its drugs that were published by the national drug pricing compendia" on the grounds that Plaintiffs fail, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer admissible evidence in support of this statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer "facts that would be admissible in evidence"); *O'Brien*, 440 F. Supp. 2d at 5 n.1 (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings). Moreover, Ivax objects to Alleged Fact No. 15 insofar as it lacks adequate foundation. *See* Fed. R. Evid. 602.

#### **PLAINTIFFS' REPLY TO STATEMENT #15:**

Ivax's dispute is obstructive and baseless. The record evidence speaks for itself:

- Q. I understand. Let's break it down. IVAX controlled the AWP's, correct?
- A. Correct. We set our AWP's.
- Q. IVAX published the AWP's knowing they were going to go to Medicaid agencies, correct?
- A. Correct.
- Q. And IVAX knew that the Medicaid agencies were going to reimburse for IVAX drugs in turn, correct?
- A. Correct.

Sarfas 3/19/09 Dep. (Exhibit H) at 37:18-38:1.

- Q. And did you over the years at Zenith Goldline and IVAX verify prices published by RedBook?
- A. Yes. That was part of my responsibility as a contract manager and pricing manager.

Q. Did you -- over the years did you also verify prices in similar reports from First DataBank?

A. Correct.

*Id.* at 193:18-24.

Q. Are you aware of any prices published by First DataBank or RedBook over the years that Zenith Goldline or IVAX contend were wrong?

A. Okay. If you're saying when they sent me out a verification or if, let's say, somebody brought to my attention, hey, you're prices may not be right, I would have done a verification, said update -- FDB, update to this correct price.

Q. Yes. I understand, and I'm saying other than that process where after a few months you would identify an incorrect price, are you aware -- and I'll be more specific to address that. Are you aware of any situation where for IVAX or Zenith Goldline drugs, AWP's and WAC's were published incorrectly by First DataBank and RedBook year after year after year?

A. Not that I'm aware of.

*Id.* at 195:12-196:9.

*See also* Plaintiffs' Replies to Statement #8, #14 and #16, which are incorporated herein.

Responding further, Ivax's dispute that the Statement does not include the reasons Ivax reported AWP's is baseless. The Statement is not concerned with the reasons Ivax reported AWP's. *See* Plaintiffs' Reply to Statement #9, which is incorporated herein.

Responding further, Ivax's argument that FDB, rather than Ivax, determined how Ivax's AWP's were set and controlled is belied by the cited record evidence (*see* Plaintiffs' Replies to Statement #14, #15, #16 and #17, which are incorporated herein), Ivax's own admissions (*see* Ivax's response to Statement # 8, which is incorporated herein) and contrary to the rulings of the Court. *See* Plaintiffs' Reply to Statement #9.

Responding further, plaintiffs object to and dispute the use of the 11/30/07 Deposition of Kay Morgan. *See* Plaintiffs' Reply to Statement #9, which is incorporated herein.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**16. Both Redbook and First Databank would send requests to Ivax to verify the accuracy of the AWP's and WACs for its drugs and Ivax would respond with corrections if errors were found. *See* Ivax 30(b)(6)(Sarfes) 8/22/07 Dep. (Exhibit G) at 254:12-256:7; Sarfas 3/19/09 Dep. (Exhibit H) at 193:18-194:3; 195:12-196:9; Exhibit I (Sarfes 3/19/09 Dep. Exhibit 21 (Excerpt of a Redbook Product Listing Verification for Ivax drugs signed 10/16/03)).**

Ivax's Response to Alleged Fact No. 16:

Ivax admits that Ivax subscribed to First DataBank and that it periodically verified the accuracy of First DataBank data with respect to Ivax's subject drugs. However, Ivax disputes Plaintiffs' characterization of these facts for the following reasons. As an initial matter, Ivax objects to this statement to the extent that it is misleading and mischaracterizes the cited testimony. As Ivax's witnesses have made clear, Ivax subscribed to First DataBank and provided and reviewed WACs and AWP's because these pricing points were a prerequisite for their products to receive First DataBank's generic indicator, and thus be selected by customers and dispensed by providers. *See* 8/22/07 Sarfas Dep. at 148-149, 323 (Ex. 11). WAC is understood in the industry to represent a maximum, invoice price, off which chargebacks and rebates to retailers or wholesalers are calculated. *See, e.g.*, 42 U.S.C. § 1395w-3a(c)(6)(B) (providing that the "term 'wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, *not including prompt pay or other discounts, rebates or reductions in price, . . . as reported in wholesale price guides or other publications of drug or biological pricing data.*") (emphasis added). First DataBank collected AWP and WAC pricing information because its entire business model was premised on providing an electronic resource for pricing points to its customers. *See* 8/22/07 Sarfas Dep. at 147 (Ex. 11). Accordingly, Ivax disputes the Plaintiffs' statement to the extent that it omits these reasons for which Ivax provided WACs and AWP's to First DataBank for the subject drugs sold by Ivax during the relevant time period. *See id.* at 253 (Ex. 11).

Furthermore, Ivax objects to Alleged Fact No. 16 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP's in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. *See* D.

Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

Moreover, Ivax disputes Plaintiffs' statement insofar as it misstates, mischaracterizes and/or misunderstands the manner in which First DataBank populates its AWP field. *See, e.g.*, 11/30/07 Morgan Dep. at 17-18, 19, 27-29, 31-33 (Ex. 6). First DataBank populates its BlueBook AWP with numbers based on surveys of wholesalers. *See id.* at 32 ("Q. Based on First DataBank's definition, AWP is a price based on information from the wholesaler, not the manufacturer, correct? A. That's correct.") (Ex. 6). Further, Ivax disputes Plaintiffs' statement to the extent that it incorrectly implies that manufacturers, and not First DataBank, are in control of populating the AWP field in the database. *Id.* at 33 ("Q. During the period when you were employed by First DataBank, the manufacturer did not decide whether First DataBank used the suggested AWP as its Blue Book AWP, correct? A. That's correct.") (Ex. 6); *id.* ("Q. During the time period when you were employed by First DataBank, manufacturers did not control the methodology used by First DataBank in populating its Blue Book AWP fields, correct? . . . A. That's correct.") (Ex. 6); *id.* ("Q. During the time period you were employed by First DataBank, manufacturers did not set the AWPs listed in First DataBank's Blue Book AWP fields, correct? ... A. That's correct.") (Ex. 6).

#### **PLAINTIFFS' REPLY TO STATEMENT #16:**

The Parties agree that Ivax subscribed to FDB and verified the accuracy of First Databank data with respect to the AWPs and WACs for its drugs. Responding further, Ivax does not dispute the facts only plaintiffs' characterization of the evidence. This means Ivax does not dispute the Statement.

Ivax's attempt to limit the Statement to First Databank only is baseless. The record evidence is that Ivax verified the accuracy of its AWPs and WACs published by RedBook. *See* Plaintiffs' Response to Statement #16, incorporated herein); *see also* Exhibit I (Sarfes 3/19/09 Dep. Exhibit 21 (Excerpt of a Redbook Product Listing Verification for Ivax drug; Ms. Sarfes corrected four Ivax AWP prices among other information and signed the Verification on October 16, 2003. ).

Responding further, Ivax's dispute that the Statement does not include the reasons Ivax reported AWP's and WAC's is nonsensical. The Statement is not concerned with the reasons, only the fact of the reporting.

Responding further, Ivax's responses concerning industry understandings of WAC are irrelevant to the statement and disputed for, *inter alia*, the reasons set forth in Plaintiffs' PSJ Mem. [Dxt# 6077] and Plaintiffs' SJ Opp. [Dkt#6147], which are incorporate herein.

Responding further, Ivax's argument that FDB, rather than Ivax, determined how Ivax's AWP's were set and controlled is belied by the cited record evidence (*see* Plaintiffs' Replies to Statement #14, #15, #16 and #17, which are incorporated herein), Ivax's own admissions (*see* Ivax's response to Statement # 8, which is incorporated herein) and contrary to the rulings of the Court. *See* Plaintiffs' Reply to Statement #9.

Responding further, plaintiffs object to and dispute the use of the 11/30/07 Deposition of Kay Morgan. *See* Plaintiffs' Reply to Statement #9, which is incorporated herein.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**17. Ivax subscribed to First Databank services to monitor both its published prices and that of its competitors. *See* Ivax 30(b)(6)(Sarfes) 8/22/07 Dep. (Exhibit G) at 256:9-20.**

Ivax's Response to Alleged Fact No. 17:

Disputed. Ivax admits that Ivax subscribed to First DataBank and that it periodically verified the accuracy of First DataBank data with respect to Ivax's subject drugs. However, as Ivax's witnesses have made clear, Ivax subscribed to First DataBank and provided and reviewed WAC's and AWP's because these pricing points were a prerequisite for their products to receive First DataBank's generic indicator, and thus be selected by customers and dispensed by providers. *See* 8/22/07 Sarfas Dep. at 148-149, 323 (Ex. 11). Ivax does not dispute that it subscribed to First DataBank publications. Ivax disputes that it subscribed to First DataBank "to monitor both its published prices and [those] of its competitors,"



and Plaintiffs have not provided any evidentiary basis for this assertion, as is required by Local Rule 56.1. *See O'Brien*, 440 F. Supp. 2d at 5 n.1.

Ivax objects to Alleged Fact No. 17 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

#### **PLAINTIFFS' REPLY TO STATEMENT #17:**

The Parties agree that Ivax subscribed to First Databank and First Data Bank publications and that it periodically verified the accuracy of FirstDatabank data with respect to Ivax drugs, which included its published AWP and WACs.

Responding further, the testimony of Ms. Sarfas, as a 30(b)(6) Ivax designee, speaks for itself:

Q. [...] Did Ivax subscribe to any FirstData Bank services?  
 A. Yes, we did.  
 Q. What did you subscribe to?  
 A. We received a CD that would provide all -- you know, basically all the products, all the pricing that they had on that CD.  
 Q. So, it was both your prices and competitors' prices?  
 A. Correct.  
 Q. Including branded price information?  
 A. Correct.

Ivax 30(b)(6)(Sarfas) 8/22/07 Dep. (Exhibit G) at 256:9-20.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

***Ivax's Published AWP's and WACs had No Relationship to Actual Prices***

**18. Ivax admits that its reported AWP's were not tethered to the actual prices that anyone pays or to the WAC. See Sarfas 3/19/09 Dep. (Exhibit H) at 33:6-34:8, 61:22-24; Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 87:22-88:4; see also Mylan, 2008 WL 5650859 at \*6.**

Ivax's Response to Alleged Fact No. 18:

Disputed. Ivax objects to Alleged Fact No. 18 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP's in setting FULs. See 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. See D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment). Furthermore, Ivax disputes that its "reported AWP's were not tethered to the actual prices that anyone pays or to the WAC, on the grounds that Plaintiffs have not provided any evidentiary basis for this assertion, as is required by Local Rule 56.1. See *O'Brien*, 440 F. Supp. 2d at 5 n.1.

**PLAINTIFFS' REPLY TO STATEMENT #18:**

The record evidence supports the Statement:

Q. (BY MR. ANDERSON) My question was different, Ms. Sarfas, and I'll rephrase it.

Did IVAX, formerly known as Zenith Goldline, publish AWP's that reflected the prices that IVAX knew customers, such as pharmacies, were paying for IVAX drugs?

A. I don't know what they were charging the pharmacies. That was not -- if I had a contract with that third-party customer, that was my contract price. What the wholesaler charged the pharmacies, I don't know. I'm not privy to that. I'm not aware of the contracts between those two entities.

Q. Did the AWP's that IVAX published reflect the prices that IVAX knew pharmacies were paying pursuant to a contract with IVAX?

A. No. It would be my contract price that I set in place.

Sarfas 3/19/09 Dep. (Exhibit H) at 33:6-34:8.

Q. What do you mean by that?

A. AWP is not linked to a contract price or a WAC price. It was linked to the price that was published. Again, established as the product came off patent at 11 -- 10 and a half to 11 percent off the brand.

Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 87:22-88:4.

Responding further, Ivax admits that its “AWP is not linked to a contract price or a WAC price”. *See* Ivax’s Response to Statement #19, which is incorporated herein in relevant part.

Responding further, Ivax’s Response that AWP prices are not relevant or material to plaintiffs’ motion is incorrect. *See* Plaintiffs’ Reply to Statement #7, which is incorporated herein.

**19. Ivax’s reported WACs and AWP’s that had no relationship to contract prices, nor could they be used to determine the actual cost of a drug to anyone. *See* Bloom 2/4/09 Dep. (Exhibit B) at 156:21-157:2; *Mylan* at \*6.**

Ivax’s Response to Alleged Fact No. 19:

Disputed. Although Ivax does not dispute that “AWP is not linked to a contract price or a WAC price,” 6/17/08 Hogan Dep. at 87:22-88:1 (Ex. 3), Ivax disputes that its reported WACs “had no relationship to contract prices, nor could they be used to determine the actual cost of a drug to anyone.” Indeed, Ms. Sarfas testified that some wholesalers pay WAC as their net price. 3/19/09 Sarfas Dep. at 79:23-80:2 (“There are some customers that actually do pay WAC.”) (Ex. 9). Ivax objects to Alleged Fact No. 19 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs’ Motion for Partial Summary Judgment. CMS did not consider AWP’s in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 (“Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can’t think of a situation where they did.”) (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs’ Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

**PLAINTIFFS’ REPLY TO STATEMENT #19:**

The parties agree that AWP is not linked to a contract price or a WAC price. Ivax does

not dispute that an AWP could not be used to determine the actual cost of a drug to anyone, nor could it reasonably do so.

Ivax's dispute that its reported WACs had no relationship to contract prices, nor could they be used to determine the actual cost of a drug to anyone is baseless. Ms. Bloom testified to these exact facts:

Q. These AWP and WAC prices, do those prices bear any relationship to contract prices?

A. No.

Q. In other words, can you look at an AWP or WAC on any given drug and gain any insight into the actual cost of the drug to anyone?

A. No.

Bloom 2/4/09 Dep. (Exhibit B) at 156:21-157:2.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**20. Ivax never calculated an average of the wholesale prices that it believed was being paid by pharmacists. *See* Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 203:9-204:16. Ivax knew that none of its customers in the competitive market pay AWP for generic drugs. *See* Bloom 2/4/09 Dep. (Exhibit B) at 24:3-4; Ivax 30(b)(6)(Sarfes) 8/22/07 Dep. (Exhibit G) at 323:18-22.**

Ivax's Response to Alleged Fact No. 20:

While Ivax does not dispute that Ivax did not "calculate[ ] an average of the wholesale prices that it believed [were] being paid by pharmacists," Ivax disputes any suggestion that it was required to calculate the actual acquisition costs paid by pharmacists for its drugs or that AWP is anything other than a reference price that Ivax sets to obtain a generic indicator from the pricing compendia. *See* 8/22/07 Sarfas Dep. at 323:18-22 (Ex. 11). Plaintiffs have not provided any evidentiary basis for any such assertions. *See O'Brien*, 440 F. Supp. 2d at 5 n.1. Further, Ivax objects to Alleged Fact No. 20 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't

think of a situation where they did.”) (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs’ Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

#### **PLAINTIFFS’ REPLY TO STATEMENT #20:**

Ivax does not dispute that it knew none of its customers in the competitive market pay AWP for generic drugs.

Ivax’s argument that there was no requirement to report actual prices as AWP is improper argument in the context of a 56.1 response.

Responding further, Ivax’s Response that AWP prices are not relevant or material to plaintiffs’ motion is incorrect. *See* Plaintiffs’ Reply to Statement #7, which is incorporated herein.

**21. Ivax knew that the real wholesale cost accounts for chargebacks, rebates, discounts and other pricing incentives and allowances that got the wholesaler to its net price. *See* Sarfas 3/19/09 Dep. (Exhibit H) at 78:23-79:3.**

#### Ivax’s Response to Alleged Fact No. 21:

Disputed. Ivax disputes Alleged Fact No. 21 on the grounds that Plaintiffs have cited no evidentiary basis for this alleged fact, as is required by Local Rule 56.1. *See O’Brien*, 440 F. Supp. 2d at 5 n.1. Further, WAC is defined as “the manufacturer’s list price . . . to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price. . . .” *See* 42 U.S.C. § 1395w-a(c)(6)(B). To the extent Plaintiffs define “real wholesale cost” as net sales price to a wholesaler, Ivax admits that it understood that wholesalers often receive chargebacks, rebates, and discounts that reduce their invoice price to their net price. Ivax disputes that all wholesalers received such chargebacks, rebates, and discounts on all products, and disputes that “real wholesale cost” is lower than WAC for all of its wholesaler customers for all products. *See* 3/19/09 Sarfas Dep. at 79:23-80:2 (“There are some customers that actually do pay WAC.”) (Ex. 9). Ivax also disputes any suggestion that WAC is anything other than a wholesaler’s invoice price or list price. *Id.* at 79:12-25 (Ex. 9); *see also* 42 U.S.C. § 1395w-3a(c)(6)(B).

#### **PLAINTIFFS’ REPLY TO STATEMENT #21:**

The parties agree Ivax understood that wholesalers often receive chargebacks, rebates,

and discounts that reduce their invoice price to their net price. Ivax admits that its WAC did not reflect such chargebacks, rebates and discounts.

Responding further, contrary to what Ivax says, the record evidence supports the Statement.

Q. (BY MR. ANDERSON) Did you or others at IVAX, to your knowledge, have an awareness that the real wholesale cost was the WAC less the chargebacks and the rebates and the discounts?

A. Correct, yes. We had that understanding, yes.

Sarfis 3/19/09 Dep. (Exhibit H) at 78:23-79:3.

Responding further, Ivax's responses concerning industry understandings of WAC are irrelevant to the statement and disputed for, *inter alia*, the reasons set forth in Plaintiffs' PSJ Mem. [Dxt# 6077] and Plaintiffs' SJ Opp. [Dkt#6147], which are incorporate herein.

**22. Approximately 90% of Ivax sales to wholesalers are subject to chargebacks. See Hogan 2/6/08 Dep. (Exhibit D) at 66:17-67:10.**

Ivax's Response to Alleged Fact No. 22:

Disputed. Ivax disputes that Alleged Fact No. 22 is material to Plaintiffs' Motion for Partial Summary Judgment. WAC is understood in the industry to represent an invoice price off of which chargebacks and rebates to retailers or wholesalers are calculated. See, e.g., 42 U.S.C. § 1395w-3a(c)(6)(B) (providing that the "term 'wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, . . . as reported in wholesale price guides or other publications of drug or biological pricing data.") (emphasis added). Further, Ivax objects to Plaintiffs' statement on the grounds that Plaintiffs fail, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence, admissible or otherwise, in support of this statement. See Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer "facts that would be admissible in evidence"); *O'Brien*, 440 F. Supp. 2d at 5 n.1. Moreover, Ivax objects to Plaintiffs' statement on the basis that it lacks adequate foundation. See Fed. R. Evid. 602.

**PLAINTIFFS' REPLY TO STATEMENT #22:**

Ivax does not dispute the Statement, but says it is immaterial and not supported by evidence.

Ivax's Response that the fact that 90% of its sales to wholesalers are subject to chargebacks is not material is incorrect. The fact that 90% of its sales to wholesalers are less than WAC due to a chargeback supports plaintiffs' position that Ivax's reporting and control of its false WACs was purposeful, intentional and knowing.

Ivax cannot reasonably dispute that the Statement is not supported by the cited record evidence as Ms. Hogan testified:

Q. And what's your best estimate as to the percentage of sales to wholesalers that would be subject to a chargeback?

MS. LEVY: Objection. Calls for speculation.

You can answer the question.

THE WITNESS: What's the percentage -- let's do it again.

BY MR. MULLIN:

Q. Yes.

A. What is the percentage of sales that come back on a chargeback?

Q. Yes.

A. I mean, there is a timing issue involved. But eventually, I would say 90 percent.

Hogan 2/6/08 Dep. (Exhibit D) at 66:17-67:10.

Responding further, Ivax's responses concerning industry understandings of WAC are irrelevant to the statement and disputed for, *inter alia*, the reasons set forth in Plaintiffs' PSJ Mem. [Dxt# 6077] and Plaintiffs' SJ Opp. [Dkt#6147], which are incorporate herein.

**23. Ivax knew that less than five (5) percent of its sales are at WAC or WAC plus. See Ivax 30(b)(6)(Sarfes) 8/22/07 Dep. (Exhibit G) at 324:1-3.**



Ivax's Response to Alleged Fact No. 23:

Disputed. Ivax disputes that Alleged Fact No. 23 is material to Plaintiffs' Motion for Partial Summary Judgment. WAC is understood in the industry to represent an invoice price off of which chargebacks and rebates to retailers or wholesalers are calculated. *See, e.g.*, 42 U.S.C. § 1395w-3a(c)(6)(B) (providing that the "term 'wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, . . . as reported in wholesale price guides or other publications of drug or biological pricing data.") (emphasis added). Further, Ivax objects to Plaintiffs' statement on the grounds that Plaintiffs fail, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence, admissible or otherwise, in support of this statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer "facts that would be admissible in evidence"); *O'Brien*, 440 F. Supp. 2d at 5 n.1. Moreover, Ivax objects to Plaintiffs' statement on the basis that it lacks adequate foundation. *See* Fed. R. Evid. 602.

**PLAINTIFFS' REPLY TO STATEMENT #23:**

Ivax does not dispute the Statement, but says it is immaterial and not supported by evidence.

Ivax's Response that the fact that less than 5% of its sales are at WAC or WAC plus is not material is incorrect. The fact that less than 5% of its sales are at WAC or WAC plus supports plaintiffs' position that Ivax's reporting and control of its false WACs was purposeful, intentional and knowing.

Ivax cannot reasonably dispute that the Statement is not supported by the cited record evidence as Ms. Sarfas testified:

Q. And with regard to the WAC your sales would be five percent or less at WAC prices?

A. Yes, WAC or WAC plus.

Ivax 30(b)(6)(Sarfas) 8/22/07 Dep. (Exhibit G) at 324:1-3.

Responding further, Ivax's responses concerning industry understandings of WAC are irrelevant to the statement and disputed for, *inter alia*, the reasons set forth in Plaintiffs' PSJ

Mem. [Dxt# 6077] and Plaintiffs' SJ Opp. [Dkt#6147], which are incorporate herein.

**24. Ivax does not set its WAC at the net price that the wholesalers pay for Ivax drugs. See Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 32:5-12. All of Ivax's contract prices to its customers were below the WAC and generated chargebacks to the wholesalers. Id. at 62:14-63:4. The net price that customers pay for Ivax drugs through a wholesaler can range from 90% to 10% of the published WAC, and on average the net prices actually paid for Ivax drugs was at a 50% discount of the published WAC. See Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 69:13-70:6.**

Ivax's Response to Alleged Fact No. 24:

Disputed. As an initial matter, Ivax disputes Alleged Fact No. 24 on the grounds that Ivax's WAC prices in many instances correlate to either the prices that Ivax charged its customers in the marketplace, or the price at which wholesalers are actually invoiced, or both. See 2/6/08 Hogan Dep. at 62-63 (Ex. 12); see also 1/24/08 Blake Dep. at 203-04 ("WAC [prices] would be changed more frequently. And the reason for that, if you want the reason for that, it's because there are some people who actually buy at WAC. . . . All the wholesalers buy at WAC.") (Ex. 1); id. at 253 ("Q. But almost nobody buys at WAC, right? A. The wholesalers are the only people that every buy at WAC, *and they buy everything at WAC.*") (emphasis supplied) (Ex. 1). Indeed, every single Ivax product sold to wholesalers is sold at WAC. Id. at 203 ("All the wholesalers buy at WAC.") (Ex. 1).

Ivax also objects to Plaintiffs' statement to the extent that it implies that WAC should be "set at the net price that the wholesalers pay for Ivax drugs." WAC is defined as "the manufacturer's list price . . . to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price. . . ." See 42 U.S.C. § 1395w-a(c)(6)(B). To the extent Plaintiffs define "net price" as net sales price to a wholesaler, Ivax admits that it understood that wholesalers often receive chargebacks, rebates, and discounts that reduce their invoice price to their net price. Ivax disputes that *all* wholesalers received such chargebacks, rebates, and discounts on all products, and disputes that "net price" is lower than WAC for all of its wholesaler customers for all products. See 3/19/09 Sarfas Dep. at 79:23-80:2 ("There are some customers that actually do pay WAC.") (Ex. 9). Ivax also disputes any suggestion that WAC is anything other than a wholesaler's invoice price or list price. Id. at 79:12-25 (Ex. 9); see also 42 U.S.C. § 1395w-3a(c)(6)(B).

With respect to the first sentence of Alleged Fact No. 24, while Ivax does not dispute that it would "sell [to] wholesalers at a WAC price, and there's discounts there, chargebacks, et cetera, to get down to net pricing, contract pricing," 6/17/08 Hogan Dep. at 32:5-12 (Ex. 3), Ivax disputes that net price is lower than WAC for all of its wholesaler customers for all products. Plaintiffs have not provided any evidentiary basis for this assertion, as is required by Local Rule 56.1. See *O'Brien*, 440 F. Supp. 2d at 5 n.1. Indeed, Ms. Sarfas testified that some wholesalers pay WAC as their net price. See 3/19/09 Sarfas Dep. at 79:23-80:2 ("There are some customers that actually do pay WAC.") (Ex. 9).

With respect to the second sentence of Alleged Fact No. 24, Ivax disputes that “[a]ll of Ivax’s contract prices to its customers were below the WAC. . . .” This alleged fact is not properly supported by the evidence in the record. *See O’Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Hogan was referring only to “major wholesalers” who pay WAC, and not to smaller wholesalers who may or may not pay WAC. 6/17/08 Hogan Dep. at 62:12-63:4 (Ex. 3).

With respect to the third sentence of Alleged Fact No. 24, Ivax disputes that the “net price that customers pay for Ivax drugs through a wholesaler can range from 90% to 10% of the published WAC. . . .” Plaintiffs have not provided any evidentiary basis for this assertion, as is required by Local Rule 56.1. *See O’Brien*, 440 F. Supp. 2d at 5 n.1.

#### **PLAINTIFFS’ REPLY TO STATEMENT #24:**

Ivax does not dispute that it does not set its WAC at the net price that the wholesalers pay for Ivax drugs.

The parties agree Ivax understood that wholesalers often receive chargebacks, rebates, and discounts that reduce their invoice price to their net price. Ivax admits that its WAC did not reflect such chargebacks, rebates and discounts.

The parties agree that for the major wholesalers, all of Ivax’s contract prices to its customers were below the WAC and generated chargebacks to those wholesalers.

Ivax’s dispute that the meaning of real wholesale cost is not lower than WAC is incorrect. *See* Plaintiffs’ Reply to Statement #21.

Ivax’s dispute that the “net price that customers pay for Ivax drugs through a wholesaler can range from 90% to 10% of the published WAC. . . .” is not supported by evidence is baseless and not made in good faith. Ms. Hogan, as an Ivax corporate representative witness, testified:

Q. I think you testified actually at your previous deposition that roughly IVAX's discount from its WAC, that is, the price it was actually selling the product to wholesalers at net was roughly 50 percent of the actual published WAC; is that correct?

A. That was an average, um-hum.

Q. Right. That is to say that IVAX

publishes a wholesale acquisition cost, but the actual costs -- net costs to the wholesalers is roughly 50 percent less than the published wholesale acquisition costs on average?

A. It's not really to the wholesalers. It's to the purchasers, yeah --

Q. Well, the wholesalers --

A. -- administering the contracts.

Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 69:13-70:6.

Responding further, Ivax mischaracterizes Mr. Blake's testimony by quoting only portions of the cited testimony in its Response. Mr. Blake explains the difference between buying at WAC and the actual sales price which is "quite a bit lower". In its full context Mr. Blake testified:

Q. And based on your experience in the pharmaceutical industry, is it true that generally as contract prices would decrease with generic products, the AWP prices would remain the same or increase?

A. Usually remain the same.

Q. They would seldom, if ever, go down.

A. Seldom, if ever.

Q. And the same would be true with regard to WAC prices?

A. WAC is a little bit -- WAC would be changed more frequently. And the reason for that, if you want the reason for that, it's because there are some people who actually buy at WAC.

Q. That would be a small percentage?

A. All the wholesalers buy at WAC. And a high WAC is a disadvantage to a -- is bad for a generic company because we pay wholesalers a percent cash discount if they pay on time, and that is paid off of the invoice price, which is WAC. So the higher that is, the higher your payment for that, even though they sell the product quite a bit lower.

1/24/08 Blake Dep. at 203-04 (Ex. 1)

Q. But almost nobody buys at WAC, right?

A. The wholesalers are the only people that ever buy at WAC, and they buy everything at WAC.

Q. They get invoiced at WAC, but almost everything they buy has some kind of a chargeback, rebate, discount of some form applicable to it?

A. I think I heard one of the wholesalers tell me 7 percent of their products they actually manage to sell at WAC. But you're right. That's as high as they could ever possibly sell a product.

1/24/08 Blake Dep. at 253 (Ex. 1).

Ivax's citation of Mr. Blake's testimony in full context does not conflict with plaintiffs' Statement and in fact supports the proposition that Ivax does not set its WAC at the net price that the wholesalers pay for Ivax drugs or that Ivax's contract prices to its customers were below the WAC and generated chargebacks to the wholesalers and that the net price that customers pay for Ivax drugs through a wholesaler is usually less than WAC.

Responding further, Ivax's responses concerning industry understandings of WAC are irrelevant to the statement and disputed for, *inter alia*, the reasons set forth in Plaintiffs' PSJ Mem. [Dxt# 6077] and Plaintiffs' SJ Opp. [Dkt#6147], which are incorporate herein.

**25. Ivax also sells its drugs to distributors, who differ from wholesalers in that the distributor buys at a net price and typically services retail independent pharmacies. See Bloom 2/4/09 Dep. (Exhibit B) at 34:11-20. Ivax does not invoice generic distributors at WAC like it does wholesalers, but instead invoices distributors at a net price, which is below WAC, and is determined based on what was being paid in the marketplace. See id. at 35:6-36:6.**

Ivax's Response to Alleged Fact No. 25:

Ivax does not dispute that, at times, it invoiced generic products to non-wholesaler distributors at prices other than WAC. To the extent Alleged Fact No. 25 purports to assert that Ivax did so on all occasions and/or with respect to all such non-wholesaler distributors, Ivax disputes such assertion on the grounds that Plaintiffs fail, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence, admissible or otherwise, in support of this statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer "facts that would be admissible in evidence"); *O'Brien*, 440 F. Supp. 2d at 5 n.1. Moreover, Ivax objects to Plaintiffs' statement on the basis that it lacks adequate foundation. *See* Fed. R. Evid. 602. Ivax states that this alleged fact is immaterial to Plaintiffs' Motion for Partial Summary Judgment.

**PLAINTIFFS' REPLY TO STATEMENT #25:**

The parties agree that Ivax invoiced generic products to non-wholesaler distributors at prices other than WAC.

Ivax cannot reasonably dispute that the Statement is not supported by the cited record evidence. The record evidence speaks for itself:

Q. What is the difference between a distributor and a wholesaler?

A. Nothing, except a distributor buys at net prices.

Q. What does that mean?

A. That means that they do not generate charge-backs. They're servicing a different population. They're not servicing contracts for the manufacturers. We're primarily servicing retail independent pharmacies.

Bloom 2/4/09 Dep. (Exhibit B) at 34:11-20

Q. Then the distributor, like Anda, purchases drugs at a net price below WAC?

A. Yes.

Q. Is there a set relationship between a purchase price to an Anda on, say, across product lines as opposed to WAC or AWP?

A. No.

Q. How is the net price determined?

A. It would be determined based on whatever the retail marketplace was paying. Some calculation below that so that the distributor could make some profit.

Q. Mark it up a little?

A. Uh-huh.

Q. So it sounds like when a McKesson or Cardinal or Amerisource purchases -- and they're classified as wholesalers, correct?

A. Correct.

Q. When they purchase, they purchase at a high WAC and then sell it below WAC creating a charge-back?

A. That's correct.

Q. But when a distributor purchases a product, they purchase at a price below WAC and then the

distributor marks it up upon sale to the ultimate customer?

A. That's correct.

*Id.* at 35:6-36:6.

Responding further, Ivax's Response that the fact that distributors buy Ivax products at net prices below WAC is not material is incorrect. The fact that distributors buy Ivax products at net prices below WAC supports plaintiffs' position that Ivax's reporting and control of its false WACs was purposeful, intentional and knowing.

**26. The WAC and AWP for Ivax drugs typically did not change even though the pricing to Ivax's customers would typically decrease over time. See Hogan 2/6/08 Dep. (Exhibit D) at 132:16-133:1; 167:3-11. Corinne Hogan testified that this occurred so customers could make more money on the reimbursement. *Id.* at 167:12-168:2.**

Ivax's Response to Alleged Fact No. 26:

Disputed. With respect to the first sentence of Alleged Fact No. 26, Ivax disputes that "the WAC and AWP for Ivax drugs typically did not change even though the pricing to Ivax's customers would typically decrease over time." This alleged fact is not properly supported by the evidence in the record, as required by Local Rule 56.1. *See O'Brien*, 440 F. Supp. 2d at 5 n.1. While Ms. Hogan testified that, in general, the prices of generic drugs decrease over time, the cited testimony that WAC and AWP "remain[ed] the same" related to a single product: Albuterol kits. 2/6/08 Hogan Dep. at 167:3-11 (Ex. 12). Further, Ivax disputes this statement because Ivax's witnesses testified that Ivax did not consider adjusting WAC and AWP levels when contract prices were being set. *See id.* at 132 (Ex. 12). In addition, Ivax objects to this statement to the extent that it is misleading and mischaracterizes the deposition testimony cited.

With respect to the second sentence of Alleged Fact No. 26, Ivax disputes that it decreased its contract prices and kept its AWP and WACs constant "so customers could make more money on reimbursement." Plaintiffs have not provided any evidentiary basis for this assertion, as is required by Local Rule 56.1. *See O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Hogan testified in the abstract only that to remain competitive, a manufacturer must have an AWP and a WAC comparable to that of its competitors.

Moreover, Ivax states that during the relevant time period Ivax had literally hundreds of NDCs. Therefore, Ivax objects to Plaintiffs' attempt to characterize, based on this limited testimony, the movement of every single contract price for every single Ivax pharmaceutical product in the whole of Ivax's product line. Ivax also disputes Plaintiffs' statement on the grounds that Plaintiff fails, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence, admissible or otherwise, in support of this



statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer “facts that would be admissible in evidence”); *O’Brien*, 440 F. Supp. 2d at 5 n.1. Moreover, Ivax objects to Plaintiffs’ statement on the basis that it lacks adequate foundation. *See* Fed. R. Evid. 602. Plaintiffs’ Motion for Partial Summary Judgment concerns specific Ivax NDCs, from a specific time frame, which had particularized movements in contract prices for varying (and drug-specific) reasons, including supply concerns, competitive reasons, and the like.

Furthermore, Ivax objects to Alleged Fact No. 26 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs’ Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 (“Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can’t think of a situation where they did.”) (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs’ Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

#### **PLAINTIFFS’ REPLY TO STATEMENT #26:**

The parties agree that, in general, the prices of generic drugs decrease over time.

Ivax’s dispute that Ms. Hogan testified only as to Albuterol kits is incorrect. Ms. Hogan testified about Albuterol kits as an exemplar and her testimony is clearly in the context of the general as it relates to decreasing contract prices and constant WACs and AWP and not specific to albuterol kits. Moreover, Ms. Hogan’s testimony clearly states that Ivax customers make more money on reimbursement when contract prices decrease and the WACs and AWP stay the same. Plaintiffs stand by their Statement and the cited record evidence, which speaks for itself:

Q. Now, I think you said that in general, over time, the prices of generic products, multi-source products, would decline. Is that right?

A. Yes.

Q. With regard to albuterol kits, were there times when the contract prices would decline, but the AWP and the WAC would either remain the same or increase?

A. Remain the same, not increase.

Q. And why would AWP and WAC remain the same if contract prices were decreasing?

A. Yeah. We talked about that before.

Had said that you have to remain competitive with your AWP and your WAC's for your customers.

Q. And in order to remain competitive, you need to have an AWP and a WAC that's comparable to your competitors?

A. Yes.

Q. And is that because the reimbursement for competitors is based on AWP and/or WAC?

A. Yeah. That's how our customers make money.

Hogan 2/6/08 Dep. (Exhibit D) at 167:3-168:2.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**27. Ivax admitted to the United States Congress that "all or substantially all" of its net revenue sales occur at more than 5% below the WAC for its drugs. *See* Exhibit J (August 15, 2003 letter from Ivax CEO Rafick Henein to Anthony Cooke Esq., Counsel for the Subcommittee on Oversight and Investigations, Committee on Energy & Commerce in response to Committee Chairmen Tauzin's and Greenwood's June 26, 2003 letter) at p. 3.**

Ivax's Response to Alleged Fact No. 27:

Disputed. While Ivax does not dispute Alleged Fact No. 27, Ivax disputes that this alleged fact is material to Plaintiffs' Motion for Partial Summary Judgment.

#### **PLAINTIFFS' REPLY TO STATEMENT #27:**

Ivax does not dispute the Statement.

Responding further, Ivax's response that the Statement is not material is incorrect. The fact that Ivax admits that "all or substantially all" of its net revenue sales occur at more than 5% below WAC supports plaintiffs' position that Ivax's reporting and control of its false WACs was purposeful, intentional and knowing.

#### ***Ivax Marketed the Spread***

**28. Ivax defined "spread" in a PowerPoint presentation as "the difference between reimbursement and net cost on scripts paid by Medicaid or PBM –**

**interchangeable with profit.” See Hogan 2/6/08 Dep. (Exhibit D) at 73:7-75:5; Blake 1/24/08 Dep. (Exhibit C) at 130:22-132:6; see also Mylan, 2008 WL 5650859 at \*6. The definition of reimbursement spread was commonly known in the pharmaceutical industry and by any competent sales person. See *id.***

Ivax’s Response to Alleged Fact No. 28:

Disputed. Ivax disputes Alleged Fact No. 28 to the extent it represents that Ivax’s “PowerPoint presentation” defines “spread” as the difference between reimbursement and net costs. As an initial matter, the testimony cited by Plaintiffs for this generalized proposition was limited in scope to sales of one drug (not at issue in Plaintiffs’ Motion for Partial Summary Judgment), Clozapine, to pharmacists. See 2/6/08 Hogan Dep. at 73-74 (Ex. 12); 1/24/08 Blake Dep. at 130-31 (Ex. 1). Further, Ivax disputes Plaintiffs’ statement because it fails to set forth the complete substance of the “PowerPoint presentation” as alleged. In particular, these very pages make clear that if Ivax’s Clozapine is dispensed in lieu of the brand product, the effect will be that the reimbursement amount for state Medicaid agencies, including New York Medicaid, will be significantly lower. See Exhibit 7 to 1/24/08 Blake Dep. (Ex. 1). Put differently, the Plaintiffs’ statements improperly omit the fact that Ivax’s marketing strategy related to Clozapine *actually saved the State money overall*. In addition, and as Ivax’s witnesses have testified, Ivax provided WACs and AWP’s because First DataBank required those pricing points in order to ensure that its publications provided data that was compatible with the systems of their customers. See 8/22/07 Sarfas Dep. at 147 (Ex. 11); 2/22/08 Shanks Dep. at 54 (“It’s a requirement by data bases that you have to give [AWP].”) (Ex. 7).

Furthermore, Ivax objects to Alleged Fact No. 28 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs’ Motion for Partial Summary Judgment. CMS did not consider AWP’s in setting FULs. See 3/19/08 Gaston Dep. at 457:21-458:7 (“Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can’t think of a situation where they did.”) (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs’ Motion for Partial Summary Judgment. See D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment).

Moreover, Ivax disputes Plaintiffs’ statement because Plaintiffs fail, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer admissible evidence in support of these statements. See Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer “facts that would be admissible in evidence”); *O’Brien*, 440 F. Supp. 2d at 5 n.1. Moreover, Ivax objects that Plaintiffs’ statement that “spread” was “commonly known in the pharmaceutical industry and by any competent sales person” lacks proper foundation. See Fed. R. Evid. 602.

Finally, Ivax disputes Alleged Fact No. 28 is material to Plaintiffs’ Motion for Partial Summary Judgment. Further, Ivax disputes any suggestion that it ever marketed the spread with respect to the products at issue in Plaintiffs’ motion, *see*,

*e.g.*, 2/4/09 Bloom Dep. at 80:25-81:23 (Ivax did not have a “strategy” to market the spread) (Ex. 4), and Plaintiffs have not provided any evidentiary basis for any such an assertion, as is required by Local Rule 56.1. *See O’Brien*, 440 F. Supp. 2d at 5 n.1.

**PLAINTIFFS’ REPLY TO STATEMENT #28:**

Plaintiffs stand by their Statement and the cited record evidence, which speaks for itself and shows that Ivax defined “spread” in a PowerPoint presentation as “the difference between reimbursement and net cost on scripts paid by Medicaid or PBM – interchangeable with profit.” Both Ms. Hogan and Mr. Blake acknowledged this fact:

Q. And the second one is spread. Are you familiar with the term spread?

A. Yes.

Q. What is spread?

A. My understanding, it's the reimbursement amount that a pharmacy would receive.

Q. How did you come to your understanding relating to the term "spread"?

A. Just through years in the office. From our original pricing managers -- Ofelia Perez, I guess, was the first person that would have introduced me to the concept.

Q. Based on your experience in the industry, is spread a commonly understood term among sales and marketing people in the pharmaceutical industry?

A. Yeah. I would think so.

Q. If you would turn to -- I guess it's

A. Okay.

Q. The term "spread" is defined there as the difference between reimbursement and the net cost on scripts paid by Medicaid or a PBM. Do you see that definition?

A. Yes. Yes, I do.

Q. And is that consistent with your understanding of the term "spread"?

A. Yeah. I'd say that's an accurate description.

Q. And by PBM, what's that?

A. Pharmacy benefit manager.

Q. And then, the second bullet point on the slide is that spread is interchangeable with profit. Is that consistent with your understanding of the term?

A. That spread is interchangeable -- I guess that would be the profit that the pharmacy gets, yes.

Q. And again, based on your experience in the industry -- I guess you start in the industry in the late '80s. Right?

A. Yes, sir.

Hogan 2/6/08 Dep. (Exhibit D) at 73:7-75:5

Q. The next slide after that, slide number 31, is: "Reimbursement terms, spread. The difference between reimbursement and net cost on scripts paid by Medicaid or PBM interchangeable with profit." Is that slide true and correct?

A. The difference between the reimbursement and net cost on scripts -- yes, that's true. It's what they're paid for a drug and what they buy a drug for is essentially what this is saying.

Q. And you knew that before you ever joined IVAX; is that right?

A. Yes, well before.

Q. And that's something that's commonly known in the pharmaceutical industry among sales professionals?

A. Yes.

Q. And would you expect any common -- any competent pharmaceutical sales representative to be familiar with the term "spread"?

A. Yes.

Blake 1/24/08 Dep. (Exhibit C) at 130:22-132:6.

Ivax's dispute that the record evidence was "limited in scope to sales of one drug" is baseless. Ms. Hogan testified about her industry knowledge from being in the industry since the 1980s.

Plaintiffs do not maintain that clozapine is a drug at issue on this motion, however, the record evidence establishes that Ivax defined spread as the difference between reimbursement

and net cost on scripts paid by Medicaid or PBM, interchangeable with profit and known in the industry.

Responding further, Ivax's contention that switching from a brand to a generic and its marketing practices saved New York Medicaid money is unsubstantiated, irrelevant to the Statement, improper argument for a Rule 56.1 Statement and requires no further response.

Responding further, Ivax's response that the Statement is not material is incorrect. Ivax's knowledge that its customers gauged profitability by analyzing spread between reimbursement prices (AWPs/WACs/FULs) and actual prices and the fact that Ivax marketed the spread supports plaintiffs' position that Ivax's reporting and control of its false AWPs and WACs was purposeful, intentional and knowing.

Responding further, Plaintiffs object to and dispute the additional citations by Ivax to the extent that they are offered to establish as fact that because Ivax did not have a strategy to market the spread that Ivax in fact did not market the spread. As shown by the record evidence Ivax's actual practice was that it did market the spread irrespective of whether it was a strategy or not.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**29. Ivax knew that spread between contract price and reimbursement was a factor in a customer's buying decision. *See* Bloom 2/4/09 Dep. (Exhibit B) at 113:2-115:24 (customer Gerimed telling Ivax it is considering spread and increased revenues); 121:18-122:21 (acknowledging that customer informed Ivax of it was interested in AWP spread). Kim Bloom, who worked with pharmaceutical pricing since 1988, testified that this was not a secret in the industry. *Id.* at 80:19-81:17.**

Ivax's Response to Alleged Fact No. 29:

Disputed. Ivax disputes Alleged Fact No. 29 because it misrepresents the cited testimony and is incomplete and misleading. Ivax is aware that pharmacies seek to make a profit on the drugs they dispense. *See* 1/24/08 Blake Dep. at 79 (Ex. 1). Indeed, as Ivax's witnesses have explained, pharmacies are running a

business and therefore presumably are making purchasing decisions based on profitability. *See* 2/6/08 Hogan Dep. at 110, 112 (Ex. 12). But these truisms do not support Alleged Fact No. 29. To the contrary, the complete deposition testimony of Ivax's witnesses plainly demonstrates that generic drug companies for the most part compete entirely on price. Moreover, this proposed fact is particularly inappropriate for piecemeal judicial fact-finding before trial because it consists of selective quotations taken out of context. The jurors should have the opportunity to assess each witnesses' testimony as it is delivered in the courtroom, without the confusion of having isolated quotes read to them from the bench at the start of the trial.

Further, Ivax disputes that "factor[s]" in a "customer's buying decision" are material to Plaintiffs' Motion for Partial Summary Judgment.

#### **PLAINTIFFS' REPLY TO STATEMENT #29:**

Ivax disputes the Statement as misleading and misrepresenting the record evidence and misleading. Ivax's dispute is baseless and not made in good faith. Plaintiffs stand by their Statement and the cited record evidence. The record evidence speaks for itself:

Q. This is another request for proposal from GeriMed from 2002 to 2004. It is directed to the Contracts Administrator.

That would be your department?

A. Yes.

Q. On this bid request, there is a request from GeriMed, you see on the first page, that the contracts administrator read all the materials carefully before processing your products for GeriMed?

A. Yes.

Q. So would you have expected whoever was bidding this or preparing a bid or submitting a bid for this in response to this request, to have read this package?

A. Yes.

Q. Go to the page that ends in the Bates number 360, if you would, please, ma'am.

A. Okay.

Q. It talks about the EmphaSys program. Do you see that?

A. Yes.

Q. Are you familiar with the EmphaSys program?

A. No, I am not.

Q. This particular paragraph says that GeriMed's members can view item codes for their



wholesaler, view products with the best spread and lowest cost, and open multiple windows to compare data.

So it looks like GeriMed is telling you that the people that are going to be purchasing the product in the end, the GPO members, can view products with the best spread; true?

A. That's what that says.

Q. Then on the same page there, there is a paragraph, Invoice Analysis - Geritrac. There is sentence that says, several items are identified during the review, including contract price discrepancies, lower priced generic products, better package size or type, therapeutic substitution opportunities, et cetera. These suggestions are made to save money through lower contract pricing or increase revenue through better spread between AWP and contract price. This review is done from a monetary perspective only; special state regulations, clinical concerns and other input must be included when reviewing changes in product selection by the member.

Did I read that correctly?

A. Yes, you did.

Q. Does it appear to you that GeriMed is considering spread and increased revenues?

MS. LEVY: Objection.

THE WITNESS: Yes, they are.

Bloom 2/4/09 Dep. (Exhibit B) at 113:2-115:

Q. It looks like the bid price on that is \$603.74?

A. Yes.

Q. And then if you carry that over to the next page, the AWP on that is \$1,313.55?

A. Yes.

Q. And there's an AWP spread on that of \$709.61?

A. That's what this says.

Q. Does this suggest to you that this customer was interested in AWP spreads?

A. Yes.

*Id.* at 122:10-21.

Q. And if then the contract price between you and your customer was equivalent but your reference

price was different, could that be a factor in making the sale?

A. It might be a factor of why the pharmacy would decide on you, I would think, but it wasn't a strategy that we had.

Q. Was that something that IVAX was aware of, that that could be a factor that the pharmacy would consider?

A. I don't think it was a secret in the industry, no. It's not a secret. We were aware of it.

Q. So then IVAX would have been aware that reimbursement spread could be a factor in a pharmacy's decision to purchase product?

A. A pharmacist is going to make a decision on whether or not he's going to make profit on his product that he's going to dispense, so, yes.

*Id.* at 80:19-81:17.

Responding further, Ivax's response that the Statement is not material is incorrect. Ivax's knowledge that its customers gauged profitability by analyzing spread between reimbursement prices (AWPs/WACs/FULs) and actual prices and the fact that Ivax marketed the spread supports plaintiffs' position that Ivax's reporting and control of its false AWPs and WACs was purposeful, intentional and knowing.

**30. Ivax would be at a competitive disadvantage if other manufacturers had higher AWPs than Ivax. *Id.* at 210:8-210:23. Ivax knew that raising an AWP did not have any ramifications on anything other than reimbursement. *Id.* at 211:9-12.**

Ivax's Response to Alleged Fact No. 30:

Disputed. Plaintiffs have failed, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence, admissible or otherwise, in support of this statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer "facts that would be admissible in evidence"); *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ivax likewise objects to Plaintiffs' statement on the basis that it lacks adequate foundation. *See* Fed. R. Evid. 602. Ivax objects to Alleged Fact No. 30 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWPs in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5).

Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment). Further, Ivax disputes that it "would be at a competitive disadvantage if other manufacturers had higher AWP's than Ivax." This alleged fact is not properly supported by the evidence in the record. *See* O'Brien, 440 F. Supp. 2d at 5 n.1. Ms. Bloom testified only that Ivax would be at a competitive disadvantage if other manufacturers had higher AWP's and Ivax's were "much lower." 2/4/09 Bloom Dep. at 210:14-2 (Ex. 4).

**PLAINTIFFS' REPLY TO STATEMENT #30:**

Ivax does not dispute that it knew that raising an AWP did not have any ramifications on anything other than reimbursement.

Ivax disputes the Statement as not being supported by evidence. Ivax's dispute is baseless. Plaintiffs stand by their Statement and the cited record evidence. The record evidence speaks for itself:

Q. And this is analyzing a price increase on WAC and AWP, correct?

A. Yes.

Q. Is there a change in anything besides AWP and WAC on this document?

A. I can't see it all. It doesn't appear.

Q. Why would IVAX raise AWP and WAC on a product but not raise contract prices, any of the pricing buckets?

A. Competitive information.

Q. What do you mean by that?

A. Other manufacturers are out there with a higher AWP and we would be at a competitive disadvantage to have ours much lower.

Q. Why is that?

A. Reimbursement.

Bloom 2/4/09 Dep. (Exhibit B) at 210:8-210:23.

Q. [...] Does changing an AWP have any ramifications on anything besides reimbursement?

MS. LEVY: Objection.

THE WITNESS: Not to my knowledge, no.

*Id.* at 211:9-12.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**31. Ivax notified customers such as RX Solutions, a mail order pharmacy, of the percentage spread between Ivax's Reported AWP and the RX solutions contract pricing. *See id.* at 87:20-90:21; Exhibit K (Bloom 2/4/09 Dep. Exhibit 4 (May 21, 2003 Price Decrease & Increase Notification to RX Solutions)).**

Ivax's Response to Alleged Fact No. 31:

Ivax objects to Plaintiffs' statement on the basis that it lacks adequate foundation. *See* Fed. R. Evid. 602. Ivax objects to Alleged Fact No. 30 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment). While Ivax does not dispute that, in response to a customer request, it provided information about the percentage difference between the AWP and the customer's contract price, Ivax disputes any suggestion by Plaintiffs that Ivax marketed the spread with respect to the products at issue in Plaintiffs' motion, *see, e.g.*, 2/4/09 Bloom Dep. at 80:25-81:23 (Ivax did not have a "strategy" to market the spread) (Ex. 4), and Plaintiffs have not provided any evidentiary basis for such an assertion. *See O'Brien*, 440 F. Supp. 2d at 5 n.1.

**PLAINTIFFS' REPLY TO STATEMENT #31:**

The parties agree that Ivax provided information about the percentage difference between the AWP and the customer's contract price.

Ivax disputes the Statement as not being supported by evidence. Ivax's dispute is baseless. Plaintiffs stand by their Statement and the cited record evidence.

Exhibit K is a May 21, 2003 Price Decrease & Increase Notification to RX Solutions from Ivax that has two column comparing AWP spreads for its customer: one column titled

“Spread between AWP & Current Price”; and, a second column titled, “Spread between AWP & New Price”. *See* Exhibit K (Bloom 2/4/09 Dep. Exhibit 4)(May 21, 2003 Price Decrease & Increase Notification to RX Solutions).

Responding further, Ivax’s Response that AWP prices are not relevant or material to plaintiffs’ motion is incorrect. *See* Plaintiffs’ Reply to Statement #7, which is incorporated herein.

Responding further, Plaintiffs object to and dispute the additional citations by Ivax to the extent that they are offered to establish as fact that because Ivax did not have a strategy to market the spread that Ivax in fact did not market the spread. As shown by the record evidence Ivax’s actual practice was that it did market the spread irrespective of whether it was a strategy or not. *See* Plaintiffs Replies to Statements #28, #29, #30, #32 and #33, which are incorporated herein.

**32. Ivax knew that the reimbursement spread basically marketed itself as it was self-evident to Ivax’s pharmacy customers for all of its drugs given that the customers knew how they would be reimbursed by Medicaid. *See* Blake 1/24/08 Dep. (Exhibit C) at 67:1-19.**

Ivax’s Response to Alleged Fact No. 32:

Disputed. Plaintiffs have failed, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence, admissible or otherwise, in support of this statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer “facts that would be admissible in evidence”); *O’Brien*, 440 F. Supp. 2d at 5 n.1. Ivax likewise objects to Plaintiffs’ statement on the basis that it lacks adequate foundation. *See* Fed. R. Evid. 602. Ivax objects to Alleged Fact No. 32 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs’ Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 (“Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can’t think of a situation where they did.”) (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs’ Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment). Further, Ivax disputes that it “knew that the reimbursement spread basically marketed itself” and also disputes any suggestion by Plaintiffs that Ivax marketed the spread for the products at issue in Plaintiffs’

motion. 2/4/09 Bloom Dep. at 80:25-81:23 (Ivax did not have a “strategy” to market the spread) (Ex. 4), and Plaintiffs have not provided any evidentiary basis for such an assertion. *See O’Brien*, 440 F. Supp. 2d at 5 n.1.

**PLAINTIFFS’ REPLY TO STATEMENT #32:**

Ivax disputes the Statement as not being supported by evidence. Ivax’s dispute is obstructive and baseless. Plaintiffs stand by their Statement and the cited record evidence. Mr. Blake clearly testified:

Q. While you were employed at IVAX, did the company ever market clozapine on the basis of the spread between what it cost to purchase the drug versus what the reimbursement was for the drug?

A. No. We never marketed it -- we never marketed that. That -- that information was always self-evident to the buyers. The buyers always knew what they would be reimbursed were they to dispense all of our drugs as far as that goes, and not only on Medicaid, but they are aware of all of the payment plans that they deal with.

So I understood what was going on, but we never marketed that, because primarily there was no need to market that. That was already a given, and just like pharmacists understood it was a given that our clozapine was bioequivalent with the brand Clozaril. It was a given. But physicians didn't understand that, and that's where we had to educate the populace.

Blake 1/24/08 Dep. (Exhibit C) at 67:1-19

Responding further, Ivax’s Response that AWP prices are not relevant or material to plaintiffs’ motion is incorrect. *See* Plaintiffs’ Reply to Statement #7, which is incorporated herein.

Responding further, Plaintiffs object to and dispute the additional citations by Ivax to the extent that they are offered to establish as fact that because Ivax did not have a strategy to market the spread that Ivax in fact did not market the spread. As shown by the record evidence Ivax’s

actual practice was that it did market the spread irrespective of whether it was a strategy or not. *See* Plaintiffs Replies to Statements #28, #29, #30, #31, #33 and #32, which are incorporated herein.

**33. If spread on Ivax drugs ever came up in discussions with pharmacists, it would be discussed. *Id.* at 82:16-83:17.**

Ivax's Response to Alleged Fact No. 33:

Disputed. Plaintiffs have failed, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence, admissible or otherwise, in support of this statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer "facts that would be admissible in evidence"); *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ivax likewise objects to Plaintiffs' statement on the basis that it lacks adequate foundation. *See* Fed. R. Evid. 602. Ivax objects to Alleged Fact No. 33 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment). While Ivax does not dispute that Mr. Blake testified that, in marketing Clozapine to specialty pharmacies, "if it ever came up about spreads, then I'm sure we would discuss it," 1/24/08 Blake Dep. at 83:8-10 (Ex. 1), Ivax disputes any suggestion that Ivax regularly discussed "spread" with pharmacists, *see, e.g.*, 2/4/09 Bloom Dep. at 80:25-81:23 (Ivax did not have a "strategy" to market the spread) (Ex. 4), and Plaintiffs have not provided any evidentiary basis for such an assertion. *See O'Brien*, 440 F. Supp. 2d at 5 n.1.

**PLAINTIFFS' REPLY TO STATEMENT #33:**

Ivax disputes the Statement as not being supported by evidence. Ivax's dispute is obstructive and baseless. Ivax's attempt to limit Mr. Blake's testimony to just specialty pharmacies is equally specious. Plaintiffs stand by their Statement and the cited record evidence. The record evidence speaks for itself:

Q. And isn't it true that part of your education process, part of what you were trying to get out there in the marketplace was pharmacists, you



can make more money by using clozapine rather than Clozaril?

MS. LEVY: Objection. Asked and answered.

You can answer.

BY MR. MULLIN:

Q. You may answer, sir.

A. Again, I'm not sure what the real question -- if your question, sir, is that you're asking me was that something that we did on a daily basis, to go around educating pharmacists, then no, that was not one of our primary goals. If it ever came up about spreads, then I'm sure we would discuss it if it ever came up with pharmacists.

But it wasn't our intent -- it was my assumption that any pharmacists that we were dealing with that's an independent pharmacist would understand this, and anybody that didn't understand it would probably be in a chain and wouldn't care. I mean, he wouldn't be getting the profits of that chain. He was just filling prescriptions.

Blake 1/24/08 Dep. (Exhibit C) at 82:16-83:17.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

Responding further, Plaintiffs object to and dispute the additional citations by Ivax to the extent that they are offered to establish as fact that because Ivax did not have a strategy to market the spread that Ivax in fact did not market the spread. As shown by the record evidence Ivax's actual practice was that it did market the spread irrespective of whether it was a strategy or not. *See* Plaintiffs Replies to Statements #28, #29, #30, #31, #32 and #34, which are incorporated herein.

**34. Ivax analyzed and prepared bid pricing based upon spread calculations between AWP and the customer's price to win the business of customers like the Pharmacy Benefits Manager ("PBM") Caremark. *See* Exhibits L (Deposition of Susan Randall dated 4/16/09 ("Randall 4/16/09 Dep.") Exhibit 14 (spreadsheet, note and email string in**

**December 2002 concerning a bid price to Caremark and the fact that it must have a spread of at least 60% between AWP and contract price to win Caremark's business)); Exhibit M (Randall 4/16/09 Dep. Exhibit 15 (email dated 7/22/03 from Susan Randall (Ivax) to James Matas (Ivax) discussing the preparation of a bid price to Caremark at 65% off of AWP)).**

Ivax's Response to Alleged Fact No. 34:

Disputed. Ivax objects to Alleged Fact No. 34 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. See 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment). Ivax does not dispute that its customer, Caremark (1) requested a spread of 60 percent between the AWP and contract price for Folic Acid 1mg tablets, and (2) requested a spread of 65 percent between the AWP and contract price for Quinine Sulfate 325mg tablets—two products that are not at issue in Plaintiffs' motion and therefore immaterial. Ivax also does not dispute that, in response to both requests, it attempted to structure its bid pricing to be responsive to Caremark's requests. Ivax disputes that, as a general practice, it "analyzed and prepared bid pricing based upon spread calculations between AWP and the customer's price." Ivax also disputes any suggestion that it marketed the spread for drugs at issue in Plaintiffs' motion, *see, e.g.*, 2/4/09 Bloom Dep. at 80:25-81:23 (Ivax did not have a "strategy" to market the spread) (Ex. 4), and Plaintiffs have not provided any evidentiary basis for such an assertion. *See O'Brien*, 440 F. Supp. 2d at 5 n.1.

**PLAINTIFFS' REPLY TO STATEMENT #34:**

The parties agree that customer, Caremark (1) requested a spread of 60 percent between the AWP and contract price for Folic Acid 1mg tablets, and (2) requested a spread of 65 percent between the AWP and contract price for Quinine Sulfate 325mg tablets. The parties also agree that Ivax attempted to structure its bid pricing to be responsive to Caremark's requests.

Responding further, Ivax's response that the Statement is not material is incorrect. Ivax's knowledge that its customers gauged profitability by analyzing spread between reimbursement prices (AWPs/WACs/FULs) and actual prices and the fact that Ivax marketed the spread

supports plaintiffs' position that Ivax's reporting and control of its false AWP and WACs was purposeful, intentional and knowing.

Plaintiffs do not maintain that Folic Acid 1mg tablets and Quinine Sulfate 325mg tablets are drugs at issue on this motion, however, the record evidence establishes that Ivax knowingly prepared its bid pricing based on percentage discounts off AWP when trying to get a customer's business.

Responding further, Plaintiffs object to and dispute the additional citations by Ivax to the extent that they are offered to establish as fact that because Ivax did not have a strategy to market the spread that Ivax in fact did not market the spread. As shown by the record evidence Ivax's actual practice was that it did market the spread irrespective of whether it was a strategy or not. *See* Plaintiffs Replies to Statements #28, #29, #30, #31, #32 and #33, which are incorporated herein.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**35. Ivax knew that if it increased its AWP in response to the competitive marketplace, which it did on occasion, that the reimbursement spread for a drug reimbursed on AWP would also increase. *See* Bloom 2/4/09 Dep. (Exhibit B) at 98:9-99:12.**

Ivax's Response to Alleged Fact No. 35:

Disputed. Ivax objects to Alleged Fact No. 35 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Ivax does not dispute that, to the extent reimbursement is based on AWP, an increase in the AWP for a particular drug will have the effect of increasing the reimbursement for that drug. Ivax disputes any suggestion that it increased its AWP to increase a customer's reimbursement

spread, and Plaintiffs have not provided any evidentiary basis for such an assertion. *See O'Brien*, 440 F. Supp. 2d at 5 n.1.

**PLAINTIFFS' REPLY TO STATEMENT #35:**

The parties agree that Ivax knew, to the extent reimbursement is based on AWP, an increase in the AWP for a particular drug will have the effect of increasing the reimbursement for that drug.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**36. Ivax knew that if it kept its AWP constant and reduced the contract price for a drug that the effect would be to increase reimbursement profit for that drug to the pharmacy when reimbursed on an AWP calculation. *See* Hogan 2/6/08 Dep. (Exhibit D) at 182:14-183:9.**

Ivax's Response to Alleged Fact No. 36:

Disputed. Ivax objects to Alleged Fact No. 36 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment). Moreover, Ivax objects to Plaintiffs' Alleged Fact insofar as it lacks adequate foundation. *See* Fed. R. Evid. 602. Ivax disputes any suggestion that it lowered its contract prices to increase a customer's reimbursement spread, and Plaintiffs have not provided any evidentiary basis for such an assertion. *See O'Brien*, 440 F. Supp. 2d at 5 n.1.

**PLAINTIFFS' REPLY TO STATEMENT #36:**

Ivax disputes the Statement as not being supported by evidence. Plaintiffs stand by their Statement and the cited record evidence. The record evidence speaks for itself:

Q. And if you look on Exhibit 15, under

step one, it says, "By switching to the generic, you can take advantage of a significant profit opportunity. Effective June 1, 1998, there was a price decrease for Zenith Goldline clozapine, while the AWP remained the same. This can significantly increase your profits on third-party prescriptions and save your private-pay patients some money."

Do you understand that statement to be true?

A. True that it's on this paper or true that --

Q. True that when you keep AWP the same but reduce the contract price, you increase the pharmacist's profits.

A. Yeah. We've talked about that today, yes.

Hogan 2/6/08 Dep. (Exhibit D) at 182:14-183:9

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**37. Ivax believed there was no competitive reason to be lower than the threshold AWP for generic designation (10% off brand AWP) because at a lower AWP its customers would make less profit on Ivax's drugs than its competitors who were at or near the threshold AWP. *See* Hogan 2/6/08 Dep. (Exhibit D) at 147:22-148:12.**

Ivax's Response to Alleged Fact No. 37:

Disputed. Ivax objects to Alleged Fact No. 37 insofar as it relies on, refers to, or otherwise mentions AWP, which has no relevance or bearing on Plaintiffs' Motion for Partial Summary Judgment. CMS did not consider AWP in setting FULs. *See* 3/19/08 Gaston Dep. at 457:21-458:7 ("Q. What role if any did AWP play in setting FULs? A. Generally, it did not. Q. Can you think of any instance in which CMS based a FUL on the published AWP price? A. I can't think of a situation where they did.") (Ex. 5). Accordingly, Ivax disputes that AWP is material to the Plaintiffs' Motion for Partial Summary Judgment. *See* D. Mass. L.R. 56.1; *St. Paul Fire and Marine Ins. Co.*, 379 F. Supp. 2d at 186 n.1 (refusing to consider immaterial facts as part of a motion for summary judgment). Moreover, Ivax objects to Plaintiffs' Alleged Fact insofar as it lacks adequate foundation. *See* Fed. R. Evid. 602.

Ivax also disputes that it "believed there was no competitive reason to be lower than the threshold AWP for generic designation (10% off brand AWP)

because at a lower AWP its customers would make less profit on Ivax's drugs than its competitors who were at or near the threshold AWP." Further, Ivax disputes any suggestion that it considered its customers' reimbursement when it set its AWP. Plaintiffs have not provided any evidentiary basis for these assertions. *See O'Brien*, 440 F. Supp. 2d at 5 n.1. Indeed, Ms. Hogan testified that, over time after the launch of a new drug, the brand AWP would increase and Ivax's AWP would remain the same, meaning that Ivax's AWP was "lower than the threshold for generic designation." 2/6/08 Hogan Dep. at 148:13-20 (Ex. 12).

### **PLAINTIFFS' REPLY TO STATEMENT #37:**

Ivax disputes the Statement as not being supported by evidence. Plaintiffs stand by their Statement and the cited record evidence. The record evidence speaks for itself:

Q. And why did the company pick the maximum amount it could set an AWP and still get brand -- generic designation?

A. The only reason I would say is for competitive reasons.

Q. Why would that help you competitively?

A. If your customers remember reimbursement equals profit on your slide -- so our customers, that's how they make money. So if we're at a competitive disadvantage because they can't make as much money on our product as they do every other generic out there, I would be at a disadvantage.

Hogan 2/6/08 Dep. (Exhibit D) at 147:22-148:12.

Responding further, Ivax's Response that AWP prices are not relevant or material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #7, which is incorporated herein.

**38. Ivax knew of the Federal Upper Limit (FUL) and that it is a limitation on reimbursement below AWP that is set on published prices. *See* Ivax 30(b)(6)(Hogan) 6/17/08 Dep. (Exhibit E) at 260:15-261:15; *see also* Bloom 2/4/09 Dep. (Exhibit B) at 144:10-145:2.**

Ivax's Response to Alleged Fact No. 38: Ivax disputes that it "knew of the Federal Upper Limit (FUL) and that it is a limitation on reimbursement below AWP that is set on published prices." Plaintiffs fail, contrary to the requirements set forth in the Federal Rules of Civil Procedure, to proffer any evidence,

admissible or otherwise, in support of this statement. *See* Fed. R. Civ. P. 56(e)(1) (requiring moving party to proffer “facts that would be admissible in evidence”); *O’Brien*, 440 F. Supp. 2d at 5 n.1. Moreover, Ivax objects to Plaintiffs’ statement on the basis that it lacks adequate foundation. *See* Fed. R. Evid. 602. In any event, Ms. Hogan testified only that she understood that there was a FUL but did not know what it was or how it was established. 6/17/08 Hogan Dep. at 260:15-261:6 (Ex. 3). Ms. Bloom testified about MACs, not FULs. 2/4/09 Bloom Dep. at 144:10-145:2 (Ex. 4).

### **PLAINTIFFS’ REPLY TO STATEMENT #38:**

Ivax disputes the Statement as not being supported by evidence. Ivax’s dispute is baseless, egregious and obstructive. Plaintiffs stand by their Statement and the cited record evidence speaks for itself. Ms. Bloom testified clearly:

Q. [...] Do you know what a MAC is?

A. Yes.

Q. So a HCFA or HIFA MAC or an individual [state] or private third party payors could establish MAC's?

A. Yes.

Q. What is a MAC?

A. A maximum allowable cost.

Q. And how would that affect reimbursement?

A. It would be the highest amount that they would pay on any product.

Q. Even though they might have a reimbursement that's AWP list ten percent plus dispensing fee, if there's a MAC in place and it's lower than that, they'll just pay the MAC?

A. That's right.

Q. Is that something that you've been aware of the whole time at IVAX?

A. Yes

Bloom 2/4/09 Dep. (Exhibit B) at 144:10-145:2.

Responding further, as a matter of law, having entered into the rebate agreements, which Ivax admits (*see* Plaintiffs’ Reply to Statement #3), Ivax was required to familiarize itself with the legal requirements, standards and procedures of the Medicaid program, including the



reimbursement formulas. *See Mylan*, 2008 WL 5650859 (D.Mass) at \*25 (citing *Heckler v. Community Health Servs.*, 467 U.S. 51, 63-65, (1984)).

**39. Ivax notified customers when a drug it sold was no longer subject to the Federal Upper Limit knowing that the reimbursement would increase once the FUL restriction was removed. *See Exhibit N (Deposition of Jon Holden dated 4/28/09 Exhibit 8 (Letters dated and February 15, 2000 and March 17, 2000 from Jon Holden (Ivax) to Lynn King (Eckerd) discussing a price increase and informing Eckerd that the Federal Upper Limit had been removed thus “eliminating any reimbursement restrictions”)).***

Ivax’s Response to Alleged Fact No. 39: Ivax disputes that Alleged Fact No. 39 is material to Plaintiffs’ Motion for Partial Summary Judgment. Ivax does not dispute that it communicated with its customers concerning price changes, and on occasion it provided information that a drug was no longer subject to a FUL. Ivax disputes that it provided such notifications on any regular or systematic basis, and Plaintiffs have not provided any evidentiary basis for such an assertion. *See O’Brien*, 440 F. Supp. 2d at 5 n.1.

#### **PLAINTIFFS’ REPLY TO STATEMENT #39:**

Ivax does not dispute the Statement, only its materiality.

Responding further, Ivax’s response that the Statement is not material is incorrect. Ivax’s knowledge that its customers gauged profitability by analyzing spread between reimbursement prices (AWPs/WACs/FULs) and actual prices and the fact that Ivax marketed changes in reimbursement supports plaintiffs’ position that Ivax’s reporting and control of its false AWPs and WACs was purposeful, intentional and knowing.

#### ***Ivax’s AMPs***

**40. At all times, from 1997 to 2005, Ivax calculated and reported the average manufacturer’s price (“AMP”) for all its products on a quarterly basis as required by the federal rebate statute. *See Sarfas 3/19/09 Dep. (Exhibit H) at 31:13-18; Bloom 2/4/09 Dep. (Exhibit B) at 142:10-18; Hogan 2/6/08 Dep. (Exhibit D) at 93:8-94:12; see also Mylan, 2008 WL 5650859 at \*30.***

Ivax’s Response to Alleged Fact No. 40:

Ivax does not dispute Alleged Fact No. 40. However, this alleged fact is not properly supported by the evidence in the record. *See O’Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Sarfas, Ms. Bloom, and Ms. Hogan all testified only concerning their general understanding that AMP was reported to CMS. 3/19/09 Sarfas Dep.

at 31:13-18 (Ex. 9); 2/4/09 Bloom Dep. at 142:10-18 (Ex. 4); 2/6/08 Hogan Dep. at 93:8-94:12 (Ex. 12).

**PLAINTIFFS' REPLY TO STATEMENT #39:**

No dispute. No further Reply is required.

Dated: June 30, 2009

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, James P. Carroll Jr., hereby certify that I caused a true and correct copy of the foregoing PLAINTIFFS' REPLY LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO IVAX CORPORATION AND IVAX PHARMACEUTICALS INC., to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: June 30, 2009

\_\_\_\_\_/s/\_\_\_\_\_  
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